

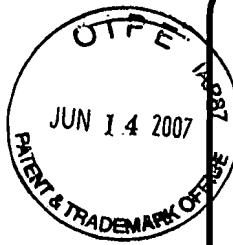
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# TRANSMITTAL FORM

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Total Number of Pages in This Submission

Application Number	09/897,295
Filing Date	June 29, 2006
First Named Inventor	William J. Boyle
Art Unit	3743
Examiner Name	Teena Kay Mitchell
Attorney Docket Number	ACSES-56001 (26361)

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input checked="" type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment / Reply	<input type="checkbox"/> Petition	<input checked="" type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
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<input type="checkbox"/> Reply to Missing Parts/ Incomplete Application	<input type="checkbox"/> Remarks	
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<b>CUSTOMER NO. 24201</b>	

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	FULWIDER PATTON LLP		
Signature			
Printed name	THOMAS H. MAJCHER		
Date	June 11, 2007	Reg. No.	31,119

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Date	June 11, 2007

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Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

**FEE TRANSMITTAL  
for FY 2007** Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$)  
**\$500.00****Complete if Known**

Application Number	09/897,295
Filing Date	June 29, 2001
First Named Inventor	William J. Boyle
Examiner Name	T. Mitchell
Art Unit	3743
Attorney Docket No.	ACSES 56001 (2636P)

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**FEE CALCULATION** (All the fees below are due upon filing or may be subject to a surcharge.)**1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fees Paid (\$)
Utility	300	150	500	250	200	100	_____
Design	200	100	100	50	130	65	_____
Plant	200	100	300	150	160	80	_____
Reissue	300	150	500	250	600	300	_____
Provisional	200	100	0	0	0	0	_____

**2. EXCESS CLAIM FEES****Fee Description**

Fee Description	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50 25
Each independent claim over 3 (including Reissues)	200 100
Multiple dependent claims	360 180

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Small Entity Fee (\$)	Fee Paid (\$)
- 20 or HP =	x	\$50.00	= \$0.00	_____	_____
HP = highest number of total claims paid for, if greater than 20.					

Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
- 3 or HP =	x	\$200.00	= \$0.00

HP = highest number of independent claims paid for, if greater than 3.

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
- 100 =	0	/ 50 0 (round up to a whole)	x \$250.00	= \$0.00

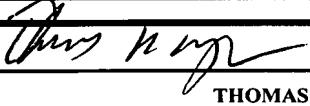
**4. OTHER FEE(S)**

Non-English specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): Appeal Brief

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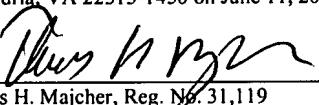
Signature		Registration No. (Attorney/Agent)	31,119	Telephone	310 824 5555
Name (Print/Type)	THOMAS H. MAJCHER		Date	June 11, 2007	

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Thomas H. Majcher, Reg. No. 31,119

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 09/897,295  
Applicant : William J. Boyle et al.  
Filed : June 29, 2001  
Title : DELIVERY AND RECOVERY SHEATHS  
FOR MEDICAL DEVICES  
Art Unit : 3743  
Examiner : Mitchell, Teena Kay

Docket No.: : ACSES 56001 (2636P)  
Customer No. : 24201

Los Angeles, California  
June 11, 2007

APPEAL BRIEF

Mail Stop Appeal Brief - PATENTS  
Commissioner for Patents  
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Alexandria, VA 22313-1450

This Appeal Brief is responsive to the Notice of Panel Decision from Pre-Appeal Brief Review dated May 10, 2007. This Appeal Brief is being filed in accordance with 37 C.F.R. § 41.37 and is being filed within one month of the mailing of the Panel's Decision. A Notice of Appeal was filed on March 2, 2007.

INTRODUCTION

The present invention is directed to delivery and recovery sheaths for use with medical devices which deliver self-expanding medical devices, such as stents and vascular grafts, for implantation in a patient's vasculature. The present invention can be used with other medical devices, such as an embolic filtering device, which generally includes a self-expanding filter basket disposed on a guide

wire. The restraining device of the present invention can be used to deliver the filtering device or stent to the target location in the patient's anatomy and/or to collapse and retrieve the filtering device once the interventional procedure has been completed.

The restraining device includes a restraining sheath having an expandable housing portion adapted to collapse and hold the self-expanding medical device. The expandable housing portion is made from an elastic material to hold the medical device in place and prevent premature deployment. The housing portion of the sheath acts to "encapsulate" the medical device, thus preventing it from being released from the sheath until the physician is ready to do so. When the present invention is utilized as a recovery sheath to recover a filtering device, the housing portion will contract to its smallest diameter as it tracks along the guide wire to reach the embolic filtering basket. As a result, the tip of the sheath should not scrape the walls of the body vessel causing a "snowplow" effect as the sheath is being advanced over the guide wire. Once the filtering basket is retrieved, the elasticity of the housing portion encapsulates the basket to prevent emboli trapped in the basket from "back washing" into the patient's vasculature.

The expandable housing portion includes one or more reinforcing members that provide additional column strength to the housing portion but do not interfere with the radial expansion or contraction of the elastic housing. These reinforcing members provide additional column strength which permits the housing portion to be made from a highly elastic material that would otherwise buckle when subjected to an applied axial force. Various configurations of this reinforcing member are recited in the dependent claims.

The present application, U.S. Serial No. 09/897,295, was filed on June 29, 2001. A Notice of Appeal was filed on January 24, 2007. This Appeal Brief is being filed in accordance with 37 C.F.R. § 41.37 and is being filed within one month of the mailing of the Panel's Decision.

### **REQUEST FOR ORAL ARGUMENT**

An oral argument is requested.

### **I. REAL PARTY IN INTEREST**

The real party in interest is ABBOTT VASCULAR, Inc., Santa Clara, California, as owner of the rights originally assigned to ADVANCED CARDIOVASCULAR SYSTEMS, INC. This

application was originally assigned by the inventors, WILLIAM J. BOYLE, ANDY E. DENNISON, BENJAMIN C. HUTER, SCOTT J. HUTER, JOHN E. PAPP, CHARLES R. PETERSON and KENT C. B. STALKER to ADVANCED CARDIOVASCULAR SYSTEMS, INC., by Assignment executed on June 26, 2001 which was recorded by the Patent Office on June 29, 2001 beginning at Reel 011971, Frame 0220.

## **II. RELATED APPEALS AND INTERFERENCES**

None.

## **III. STATUS OF CLAIMS**

This patent application has pending claims under consideration. Pending claims 3-13, 20-26 and 41-51 were finally rejected in a final Office Action dated October 24, 2006.

Claims 3-13, 20-26 and 41-51 are pending in the application and the rejection of claims 3-13, 20-26 and 41-51 is being appealed. A copy of the appealed claims is attached hereto as Exhibit 1.

Claims 3-13, 20-26 and 41-51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,544,279 to Hopkins et al. (the "Hopkins patent") in view of U.S. Patent No. 6,123,715 to Amplatz (the "Amplatz patent") and U.S. Patent No. 6,517,765 to Kelley (the "Kelley patent").

A copy of the Hopkins patent is attached hereto as Exhibit 2. A copy of the Amplatz patent is attached hereto as Exhibit 3 and a copy of the Kelley patent is attached as Exhibit 4.

## **IV. STATUS OF AMENDMENTS**

### **Office Action Dated April 29, 2004** (a copy of which is attached as Exhibit 5)

In an Office Action dated April 29, 2004 the Examiner:

- issued an election of species requirement to the pending claims.

### **Response Dated June 1, 2004** (a copy of which is attached as Exhibit 6)

In a Response dated June 1, 2004, Applicant:

- Elected the invention directed to the Species of FIGS. 1-3, 4-5 and 14-16 and withdrew claims 14-19 and 27-40 from prosecution.

**Office Action Dated August 27, 2004** (a copy of which is attached as Exhibit 7)

In an Office Action dated August 27, 2004, the Examiner:

- rejected claims 1, 2 and 20 under 35 U.S.C. § 102(e) as being anticipated by the Hopkins patent; and
- rejected claims 3-13 and 21-26 22 under 35 U.S.C. § 103(a) as being unpatentable over the Hopkins patent in view of U.S. Patent No. 6,544,279 to Cryer (the "Cryer patent").

**Amendment Dated November 29, 2004** (a copy of which is attached as Exhibit 8)

In an Amendment Dated November 29, 2004, Applicant:

- canceled without prejudice claims 1 and 2;
- re-wrote dependent claim 3 in independent form;
- added new claims 41-51; and
- presented arguments to overcome the rejections based on the Hopkins patent and the combination of the Hopkins patent and the Cryer patent.

**Office Action Dated February 24, 2005** (a copy of which is attached as Exhibit 9)

In an Office Action dated February 24, 2005, the Examiner:

- withdrew the previous rejections of claims 3-13 and 21-26 under 35 U.S.C. § 103(a); and
- rejected claims 3-13, 20-26 and 41-51 under 35 U.S.C. § 103(a) as being unpatentable over the Hopkins patent in view of the Amplatz patent.

**Amendment dated May 20, 2005** (a copy of which is attached as Exhibit 10)

In an Amendment dated May 20, 2005, Applicant:

- amended independent claim 3 to include the recitation that reinforcing member does not interfere with the expansion of the housing portion; and
- presented arguments to overcome the rejections under 35 U.S.C. § 103(a).

**Final Office Action Dated September 29, 2005** (a copy of which is attached as Exhibit 11)

In a final Office Action dated September 29, 2005, the Examiner:

- rejected claims 3-13, 20-26 and 41-51 under 35 U.S.C. § 103(a) as being unpatentable over the Hopkins patent in view of the Amplatz patent and in further view of the Kelley patent.

**Amendment After Final Dated November 29, 2005** (a copy of which is attached as Exhibit 12)

In an Amendment After Final dated November 29, 2005, Applicant:

- amended independent claim 3 to include the recitation that reinforcing member is non-woven; and
- presented arguments to overcome the rejections under 35 U.S.C. § 103(a).

**Advisory Action Dated December 21, 2005** (a copy of which is attached as Exhibit 13)

In an Advisory Action dated December 21, 2005, the Examiner refused entry of the Amendment After Final dated November 29, 2005 on the grounds that the amendment raised new issues and required a new search.

**RCE Dated December 29, 2005** (a copy of which is attached as Exhibit 14)

In an RCE dated December 29, 2005, Applicant resubmitted the previously presented Amendment.

**Office Action Dated March 20, 2006** (a copy of which is attached as Exhibit 15)

In an Office Action dated March 20, 2006, the Examiner:

- again rejected claims 3-13, 20-26 and 41-51 under 35 U.S.C. § 103(a) as being unpatentable over the Hopkins patent in view of the Amplatz patent and in further view of the Kelley patent.

**Amendment Dated June 16, 2006** (a copy of which is attached as Exhibit 16)

In an Amendment dated June 16, 2006, Applicant:

amended claims 3 and 41 to clarify that the reinforcing member does not interfere with the expansion or contraction of the housing portion; and

- presented arguments to overcome the rejections under 35 U.S.C. § 103(a).

**Final Office Action Dated September 11, 2006** (a copy of which is attached as Exhibit 17)

In a final Office Action dated October 24, 2006, the Examiner:

- maintained the rejection of claims 3-13, 20-26 and 41-51 under 35 U.S.C. § 103(a) as being unpatentable over the Hopkins patent in view of the Amplatz patent and in further view of the Kelley patent.

**Amendment After Final Dated November 8, 2006** (a copy of which is attached as Exhibit 18)

In an Amendment After Final dated November 8, 2006, Applicant:

- amended independent claim 3 to delete the recitation that reinforcing member is non-woven; and
- presented arguments to overcome the rejections under 35 U.S.C. § 103(a).

**Advisory Action Dated January 4, 2007** (a copy of which is attached as Exhibit 19)

In an Advisory Action dated January 4, 2007, the Examiner entered the Amendment After Final dated November 8, 2006 for purposes of appeal.

**Notice of Appeal Dated March 2, 2007** (a copy of which is attached as Exhibit 20)

A Notice of Appeal dated March 2, 2007 was filed by the Applicant.

**Pre-Appeal Brief Request for Review Dated March 2, 2007** (a copy of which is attached as Exhibit 21)

In a Pre-Appeal Brief Request for Review Dated March 2, 2007, the Applicant:

- presented argument to overcome the rejections under 35 U.S.C. § 103(a).

## **V. SUMMARY OF CLAIMED SUBJECT MATTER**

The present invention relates to delivery and recovery sheaths for use with medical devices which deliver self-expanding medical devices, such as stents and vascular grafts, for implantation in a patient's vasculature. The restraining device includes a restraining sheath having an expandable housing portion adapted to collapse and hold the self-expanding medical device. The expandable housing portion is made from an elastic material to hold the medical device in place and prevent premature deployment. The housing portion of the sheath acts to "encapsulate" the medical device, thus preventing it from being released from the sheath until the physician is ready to do so. When the present invention is utilized as a recovery sheath to recover a filtering device, the housing portion will contract to its smallest diameter as it tracks along the guide wire to reach the embolic filtering basket. As a result, the tip of the sheath should not scrape the walls of the body vessel causing a "snowplow" effect as the sheath is being advanced over the guide wire. Once the filtering basket is retrieved, the elasticity of the housing portion encapsulates the basket to prevent emboli trapped in the basket from "back washing" into the patient's vasculature.

The expandable housing portion includes one or more reinforcing members that provide additional column strength to the housing portion but do not interfere with the radial expansion or contraction of the elastic housing. These reinforcing members permits the housing portion to be made from a highly elastic material that could possible buckle when subjected to an applied axial force.

**Independent claim 3 is supported by at least the following references to the specification, reference characters, and figures:**

3. A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath (page 11, lines 10-20, FIGS. 1-3, # 22; page 14, lines 8-14, FIGS. 4-5, # 64; page 15, lines 20-27, FIGS. 6-7, # 78) having an expandable housing portion (page 11, lines 10-20, FIGS. 1-3, # 22; page 14, lines 8-17, FIGS. 4-5, # 62; page 15, lines 20-23, FIGS. 6-7, # 76) adapted to receive and maintain the self-expanding medical device (page 11, lines 10-20, FIGS. 2 and 16, #34) in a collapsed condition on the delivery device (page 11, lines 10-20, FIGS. 2 and 16, #38), the expandable housing portion being adapted to move between a contracted position (FIGS. 4 and 6) and expanded position (FIGS. 5 and 7), the housing portion having sufficient column strength to maintain the self-expanding medical device in its collapsed condition on its delivery device, wherein:

the expandable housing portion is made primarily from an elastic material (page 14, lines 8-24, FIGS. 4-5, # 66; page 15, lines 20-25, FIGS. 6-7, # 82) which is movable between the contracted position and expanded position and includes at least one reinforcing member (page 14, lines 8-21, FIGS. 4-5, # 68; page 15, lines 20-32, FIGS. 6-7, # 80) associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion (page 15, line 33-page 16, line 1).

**Independent claim 41 is supported by at least the following references to the specification, reference characters, and figures:**

41. A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath (page 11, lines 10-20, FIGS. 1-3, # 22; page 14, lines 8-14, FIGS. 4-5, # 64; page 15, lines 20-27, FIGS. 6-7, # 78) having an expandable housing portion (page 11, lines 10-20, FIGS. 1-3, # 22; page 14, lines 8-17, FIGS. 4-5, # 62; page 15, lines 20-23, FIGS. 6-7, # 76) adapted to move between a contracted position (FIGS. 4 and 6) and an expanded position (FIGS. 5 and 7) and to maintain the self-expanding medical device (page 11, lines 10-20, FIGS. 2 and 16, # 34) in a collapsed condition on the delivery device (page 11, lines 10-20, FIGS. 2 and 16, #38), and a reinforcing member (page 14, lines 8-21, FIGS. 4-5, # 68; page 15, lines 20-32, FIGS. 6-7, # 80), associated with the expandable housing portion to cooperatively provide sufficient strength to the expandable housing portion to maintain the self-expanding medical device in its collapsed condition on its delivery device without the reinforcing member interfering with the ability of the expandable housing portion to move between the contracted and expanded positions (page 15, line 33-page 16, line 1).

## **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

In the final Office Action dated September 11, 2006, the Examiner rejected claims 3-13, 20-26 and 41-51 as being unpatentable under 35 U.S.C. § 103(a) over the Hopkins patent in view of the Amplatz patent and the Kelley patent

In view of the Examiner's rejections, Appellant respectfully submits that the sole issue on appeal is as follows:

**Issue 1.** Are claims 3-13, 20-26 and 41-51 unpatentable under 35 U.S.C. § 103(a) over the Hopkins patent in view of the Amplatz patent and the Kelley patent.

## **VII. ARGUMENT**

### **Issue 1.**

Claims 3-13, 20-26 and 41-51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Hopkins patent in view of the Amplatz patent and the Kelley patent. The Hopkins patent discloses a retrieval sheath including an expandable housing portion used to retrieve a filter. The Examiner has taken the position that the Hopkins patent discloses a housing portion made primarily from an elastic material which is movable between a contracted position and expanded position, but

has admitted that the Hopkins patent fails to disclose a reinforcing member which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion. All of the pending claims include the recitation of a reinforcing member. The Examiner relies on the embodiment of Figures 23A and 23B in the Hopkins patent as the primary reference. First, it is noted that the retrieval sheath 592 and expandable end region 594 (the housing portion) of the Hopkins device already possesses sufficient column strength as evidenced when the expander 590 moves into the end region 594 to radially expand it in order to form a larger opening to retrieve the filter 580.

Figures 23A and 23B of the Hopkins patent, relied upon by the Examiner in rejecting the pending claims, are reproduced herein.

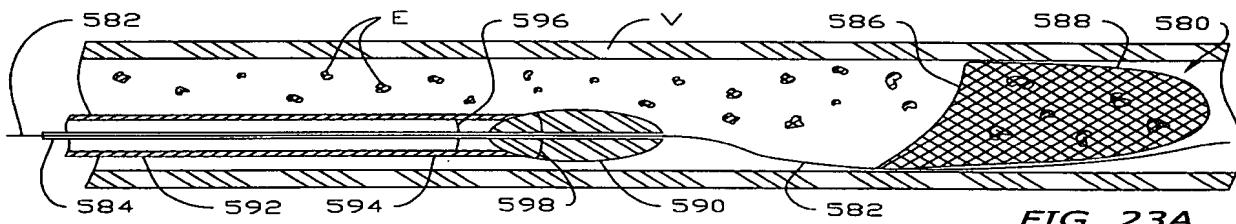


FIG. 23A

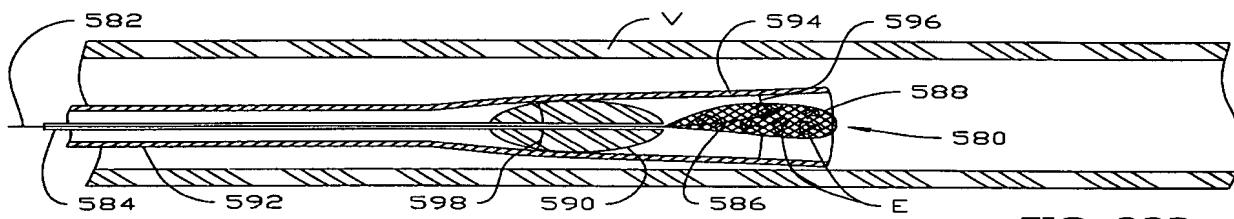


FIG. 23B

Reference is initially made to Figure 23B of the Hopkins patent which clearly shows that the distal end region 594 of the retrieval sheath 592 remains "unbunched" after being radially stretched by the expander 590. The end region 594 of the retrieval sheath 592 must possess sufficient column strength in order to allow the expander 590 to move within the opening to radially expand the tubing. Otherwise, if the end region 594 did not possess enough column strength, then the end region 594 would "bunch" upon itself, much like the bellows of an accordion, when the expander 590 contacts the end region 594 and applies an axial force.

The Hawkins patent thus fails to disclose the use or need for **any** reinforcing member with its housing since the housing already has sufficient column strength to retrieve the filter 580. The sheath 592 already possess sufficient column strength as evidenced by the expander's ability to

radially expand the end region 594 without causing bunching. If the end region 594 did not possess sufficient column strength, then the expander 590 would crush the tubing longitudinally as the expander 590 is drawn into the end region 594. Therefore, one skilled in the art would **see no need or reason** to increase the column strength of the Hopkins retrieval sheath 592 with any type of reinforcing member.

Figure 23B of the Hopkins patent also shows that the distal end region 594 of the retrieval sheath 592 does not move **between** a contracted position and an expanded condition as recited in claims 3 and 41. Rather, the distal end region 594 only moves **from** a contracted position to an expanded position as is depicted in Figures 23A and 23B above. Once the distal end region 594 is moved into the expanded position by the expander 590, it remains fully expanded as depicted in Figure 23B. It does not move back to the collapsed position since it appears that the distal end region 594 has been plastically deformed into the expanded position. If the distal end region 594 were capable of moving between expanded and collapsed positions, then the distal end region 594 would be in contact with the filter 586. This disclosure further supports Appellant's position that the retrieval sheath 592 of the Hopkins patent is sufficiently strong such that reinforcing members would not be needed to provide any additional strength.

As stated above, the Examiner has admitted that the Hopkins patent fails to disclose a reinforcing member which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion. The Examiner stated the following in the Final Office Action dated September 29, 2005 (Exhibit 11):

The difference between Hopkins and claim 3 is a reinforcing member associate therewith which provides additional column strength to the housing portion but does not interfere with the expansion of the housing portion. (page 4, lines 7-9).

The Examiner relies on two patents, the Amplatz patent and the Kelley patent, to supply the missing element from the Hopkins patent. However, the Amplatz patent simply discloses a method for forming intravascular devices using resilient metal fabric. The Examiner relies on an innocuous statement appearing in the Amplatz patent that describes the metal fabric used in the Amplatz method as being a tubular braid that has been used in the medical device field to reinforce the walls of guiding catheters. That statement in the Amplatz patent reads as follows:

In the fabric of FIG. 1A, the metal strands define two sets of essentially parallel generally helical strands, with the strands of one set having a "hand", i.e. a direction of rotation,

opposite that of the other set. This defines a generally tubular fabric, known in the fabric industry as a tubular braid. Such tubular braids are well known in the fabric arts and find some applications in the medical device field as tubular fabrics, such as in reinforcing the wall of a guiding catheter. As such braids are well known, they need not be discussed at length here. (Exhibit 3, Column 3, lines 39-48, emphasis added).

However, as will be discussed in greater detail below, this statement appearing in the Amplatz patent and its disclosure simply fails to provide the missing elements from the Hopkins patent.

The Kelley patent provides even less support for the Examiner's position. The Kelley patent is merely directed to a method for fabricating flexible and reinforcing tubing and simply teaches that the pitch and/or braid pick counts of the woven fabric and braid can be selected to affect the flexibility of the tubing into which they are formed. The Examiner has taken the position that it would have been obvious to modify the expandable housing portion of the Hopkins device by adding the woven braids disclosed in the Amplatz and Kelley patents. However, Appellant submits that the housing portion disclosed in the Hopkins patent, as discussed above, already possesses sufficient column strength and that there would be no need or reason to utilize reinforcing members to increase column strength of the tubing used to form the housing.

Even assuming *arguendo* that one would still want to increase the column strength of the Hopkins sheath 584, claims 3 and 41 require the reinforcing member to increase the column strength of the housing portion **without** interfering with the expansion or contraction of the housing portion. The Amplatz patent simply states that tubular braids have been used to reinforce the walls of a guiding catheter. Guiding catheters are generally designed to be laterally flexible and will revert to a pre-formed shape once inserted in a patient's vasculature. In this regard, a guiding catheter will be inserted into the patient's vasculature in a relative linear configuration and will then revert to its pre-formed shape after reaching its target location. While this structure may require lateral flexibility along the length of the guiding catheter, it does not require the ability to expand or collapse, since the tubular structure of the guiding catheter is not designed to expand or collapse radially. For this reason, tubular braids have been used to reinforce the wall of the guiding catheter since the intertwining braid geometry is designed to inhibit expansion and collapse, but will allow the needed lateral or longitudinal flexibility. Simply put, the use of a woven braid with an expandable housing would inhibit radial contraction and expansion of the housing.

The sheath in the Hawkins patent is designed to radially expand as it contacts the expander. However, a woven braid placed on or into an expandable sheath would inhibit the sheath from expanding

or contracting radially. Thus, the tubular braid of the Amplatz patent would inhibit expansion of the sheath. The Kelley patent merely teaches that the pitch and/or braid pick counts of the woven braid can be selected to affect the **flexibility** of the tubing into which they are formed. Therefore, lateral flexibility can be changed. However, woven braids or fabrics described in the Amplatz and Kelley patents would still inhibit **expansion or collapse** of the elastic tubing. Therefore, while one can increase or decrease the lateral flexibility of the tubing by varying the pitch or braid count, as taught by the Amplatz and Kelley patents, the woven braid or fabric will still inhibit expansion and collapse of the tubing. Therefore, the combination of the Hopkins patent with the Amplatz and Kelley patent simply fails to create the structure recited in the pending claims.

In summation, the Hopkins patent fails to disclose the basic elements recited in the pending claims. Moreover, one skilled in the art would be no need or reason to add reinforcing members to the particular sheath disclosed in the Hopkins patent. The Amplatz and Kelley patents only disclose structure which would inhibit expansion and collapse of the housing portion. Thus, the suggested combination of these patents would not create the structure recited in the pending claims.

### **CONCLUSION**

For the foregoing reasons, it is submitted that the present invention as claimed is not unpatentable over the Hopkins patent in view of the Amplatz and Kelley patents and the Examiner's rejection of claims 3-13, 20-26 and 41-51 was erroneous.

### **VIII. CLAIMS APPENDIX**

PLEASE SEE EXHIBIT 1.

### **IX. EVIDENCE EXHIBIT**

<u>EXHIBIT</u>	<u>DESCRIPTION</u>
1.	Appealed Claims.
2.	U.S. Patent No. 6,544,279 to Hopkins et al.
3.	U.S. Patent No. 6,123,715 to Amplatz.
4.	U.S. Patent No. 6,517,765 to Kelley (the "Kelley patent").
5.	Office Action Dated April 29, 2004.
6.	Response Dated June 1, 2004.

<u>EXHIBIT</u>	<u>DESCRIPTION</u>
7.	Office Action Dated August 27, 2004.
8.	Amendment Dated November 29, 2004.
9.	Office Action Dated February 24, 2005.
10.	Amendment dated May 20, 2005.
11.	Final Office Action Dated September 29, 2005.
12.	Amendment After Final Dated November 29, 2005.
13.	Advisory Action Dated December 21, 2005.
14.	RCE Dated December 29, 2005.
15.	Office Action Dated March 20, 2006.
16.	Amendment Dated June 16, 2006.
17.	Final Office Action Dated September 11, 2006.
18.	Amendment After Final Dated November 8, 2006.
19.	Advisory Action Dated January 4, 2007.
20.	Notice of Appeal Dated March 2, 2007.
21.	Pre-Appeal Brief Request for Review Dated March 2, 2007.

**X. RELATED PROCEEDINGS EXHIBIT**

None.

In the event there are any further charges associated with the filing of the subject Appeal Brief, the Director of Patents and Trademarks is hereby authorized to charge our Deposit Account No. 06-2425.

Respectfully submitted,

FULWIDER PATTON LLP

By:   
THOMAS H. MAUCHER  
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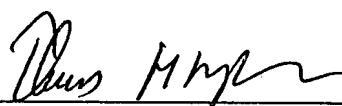
**X. RELATED PROCEEDINGS EXHIBIT**

None.

In the event there are any further charges associated with the filing of the subject Appeal Brief, the Director of Patents and Trademarks is hereby authorized to charge our Deposit Account No. 06-2425.

Respectfully submitted,

FULWIDER PATTON LLP

By:   
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Customer No. 24201

**CLAIMS ON APPEAL:**

3. (Previously Presented) A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath having an expandable housing portion adapted to receive and maintain the self-expanding medical device in a collapsed condition on the delivery device, the expandable housing portion being adapted to move between a contracted position and expanded position, the housing portion having sufficient column strength to maintain the self-expanding medical device in its collapsed condition on its delivery device, wherein:

the expandable housing portion is made primarily from an elastic material which is movable between the contracted position and expanded position and includes at least one reinforcing member associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion.

4. (Previously Presented) The restraining device of claim 3, further including:

a plurality of reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion.

5. (Previously Presented) The restraining device of claim 4, wherein:

the reinforcing members extend substantially along the length of the expandable housing portion but do not interfere with the expansion of the elastic material.

6. (Previously Presented) The restraining device of claim 5, wherein:

the reinforcing members are elongated bar-like members made from a material having high stiffness.

7. (Original) The restraining device of claim 3, wherein:

the elastic material is selected from a group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAX.

8. (Previously Presented) The restraining device of claim 4, wherein:

the reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.

9. (Previously Presented) The restraining device of claim 8, wherein:  
the reinforcing members are loaded with a material having high radiopacity.
10. (Previously Presented) The restraining device of claim 3, wherein:  
the expandable housing portion is made from a substantially tubular-shaped material which is highly elastic and includes a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion.
11. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing members are disposed within the elastic material forming the expandable housing portion.
12. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing members are attached to the surface of the expandable housing portion.
13. (Previously Presented) The restraining device of claim 4, wherein:  
each reinforcing member is disposed along the expandable housing portion to provide additional column strength to the housing portion but does not interfere with the expansion of the housing portion.

14-19. (Withdrawn)

20. (Previously Presented) The restraining device of claim 3, wherein:  
the expandable housing portion includes a low expansion section with at least one expansion member disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position.
21. (Previously Presented) The restraining device of claim 3, wherein:

the expandable housing portion includes a plurality of low expansion sections and a plurality of expansion members disposed between low expansion sections.

22. (Original) The restraining device of claim 21, wherein:

the low expansion sections are made from a material loaded with a material having high radiopacity.

23. (Original) The restraining device of claim 21, wherein:

the expansion members are made from an elastic material selected from a group which includes polyurethane, silicone, polyisoprene and lower durometer PEBAK.

24. (Original) The restraining device of claim 23, wherein:

the low expansion sections are made from a material selected from a group including cross-linked HDPE, polyolefin and polyamide.

25. (Original) The restraining device of claim 21, wherein:

the expansion members extend longitudinally along the length of the expandable housing portion.

26. (Original) The restraining device of claim 25, wherein:

the expansion members include means for preventing the low expansion sections from tearing as the expandable housing portion expands from the contracted position to the expanded position.

27-32. (Withdrawn)

33-40. (Canceled)

41. (Previously Presented) A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath having an expandable housing portion adapted to move between a contracted position and an expanded position and to maintain the self-expanding medical device in a collapsed condition on the delivery device, and a reinforcing member

associated with the expandable housing portion to cooperatively provide sufficient strength to the expandable housing portion to maintain the self-expanding medical device in its collapsed condition on its delivery device without the reinforcing member interfering with the ability of the expandable housing portion to move between the contracted and expanded positions.

42. (Previously Presented) The restraining device of claim 41, further including:  
a plurality of reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion but which do not interfere with the ability of the expandable housing to move between the contracted and expanded positions.
43. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is embedded in the wall which forms the expandable housing portion.
44. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is an elongated bar-like member made from a material having a stiffness higher than the stiffness of the material used to form the expandable housing portion.
45. (Previously Presented) The restraining device of claim 41, wherein:  
the expandable housing portion is made from an elastic material selected from a group of materials which includes silicone, polyurethane, polyisoprene, and low durometer PEBAX.
46. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.
47. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is loaded with a material having high radiopacity.
48. (Previously Presented) The restraining device of claim 41, wherein:

the expandable housing portion is made from a substantially tubular-shaped material which is highly elastic and includes a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion.

49. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is molded within the material used to form the expandable housing portion.
50. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is attached to the surface of the expandable housing portion.
51. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member helps to bias the expandable housing portion in the contracted position.

181656.1

**CLAIMS ON APPEAL:**

3. (Previously Presented) A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath having an expandable housing portion adapted to receive and maintain the self-expanding medical device in a collapsed condition on the delivery device, the expandable housing portion being adapted to move between a contracted position and expanded position, the housing portion having sufficient column strength to maintain the self-expanding medical device in its collapsed condition on its delivery device, wherein:

the expandable housing portion is made primarily from an elastic material which is movable between the contracted position and expanded position and includes at least one reinforcing member associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion.

4. (Previously Presented) The restraining device of claim 3, further including:

a plurality of reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion.

5. (Previously Presented) The restraining device of claim 4, wherein:

the reinforcing members extend substantially along the length of the expandable housing portion but do not interfere with the expansion of the elastic material.

6. (Previously Presented) The restraining device of claim 5, wherein:

the reinforcing members are elongated bar-like members made from a material having high stiffness.

7. (Original) The restraining device of claim 3, wherein:

the elastic material is selected from a group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAK.

8. (Previously Presented) The restraining device of claim 4, wherein:

the reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.

9. (Previously Presented) The restraining device of claim 8, wherein:  
the reinforcing members are loaded with a material having high radiopacity.

10. (Previously Presented) The restraining device of claim 3, wherein:  
the expandable housing portion is made from a substantially tubular-shaped material which is highly elastic and includes a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion.

11. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing members are disposed within the elastic material forming the expandable housing portion.

12. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing members are attached to the surface of the expandable housing portion.

13. (Previously Presented) The restraining device of claim 4, wherein:  
each reinforcing member is disposed along the expandable housing portion to provide additional column strength to the housing portion but does not interfere with the expansion of the housing portion.

14-19. (Withdrawn)

20. (Previously Presented) The restraining device of claim 3, wherein:  
the expandable housing portion includes a low expansion section with at least one expansion member disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position.

21. (Previously Presented) The restraining device of claim 3, wherein:

the expandable housing portion includes a plurality of low expansion sections and a plurality of expansion members disposed between low expansion sections.

22. (Original) The restraining device of claim 21, wherein:

the low expansion sections are made from a material loaded with a material having high radiopacity.

23. (Original) The restraining device of claim 21, wherein:

the expansion members are made from an elastic material selected from a group which includes polyurethane, silicone, polyisoprene and lower durometer PEBAX.

24. (Original) The restraining device of claim 23, wherein:

the low expansion sections are made from a material selected from a group including cross-linked HDPE, polyolefin and polyamide.

25. (Original) The restraining device of claim 21, wherein:

the expansion members extend longitudinally along the length of the expandable housing portion.

26. (Original) The restraining device of claim 25, wherein:

the expansion members include means for preventing the low expansion sections from tearing as the expandable housing portion expands from the contracted position to the expanded position.

27-32. (Withdrawn)

33-40. (Canceled)

41. (Previously Presented) A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath having an expandable housing portion adapted to move between a contracted position and an expanded position and to maintain the self-expanding medical device in a collapsed condition on the delivery device, and a reinforcing member

associated with the expandable housing portion to cooperatively provide sufficient strength to the expandable housing portion to maintain the self-expanding medical device in its collapsed condition on its delivery device without the reinforcing member interfering with the ability of the expandable housing portion to move between the contracted and expanded positions.

42. (Previously Presented) The restraining device of claim 41, further including:  
a plurality of reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion but which do not interfere with the ability of the expandable housing to move between the contracted and expanded positions.
43. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is embedded in the wall which forms the expandable housing portion.
44. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is an elongated bar-like member made from a material having a stiffness higher than the stiffness of the material used to form the expandable housing portion.
45. (Previously Presented) The restraining device of claim 41, wherein:  
the expandable housing portion is made from an elastic material selected from a group of materials which includes silicone, polyurethane, polyisoprene, and low durometer PEBAX.
46. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.
47. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is loaded with a material having high radiopacity.
48. (Previously Presented) The restraining device of claim 41, wherein:

the expandable housing portion is made from a substantially tubular-shaped material which is highly elastic and includes a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion.

49. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is molded within the material used to form the expandable housing portion.
50. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is attached to the surface of the expandable housing portion.
51. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member helps to bias the expandable housing portion in the contracted position.

MAY 03 2004



## UNITED STATES PATENT AND TRADEMARK OFFICE

FULWIDER PATTON LEE & UTECHT, LLP  
LOS ANGELES

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
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P.O. Box 1450  
Alexandria, Virginia 22313-1450  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,295	06/29/2001	William J. Boyle	ACS-56001 (26361)	1994
24201	7590	04/29/2004	EXAMINER	
FULWIDER PATTON LEE & UTECHT, LLP HOWARD HUGHES CENTER 6060 CENTER DRIVE TENTH FLOOR LOS ANGELES, CA 90045			ODLAND, KATHRYN P	
			ART UNIT	PAPER NUMBER
			3743	
DATE MAILED: 04/29/2004				

*THM*  
Response Due May 29, 2004  
Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/897,295	BOYLE ET AL.	
<b>Examiner</b>	<b>Art Unit</b>		
Kathryn Odland	3743		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 29 June 2001.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) \_\_\_\_\_ is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) 1-40 are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892) .  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.  
\_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species 1: Figures 1-3 and 14-16

Expandable housing subspecies:

Subspecies A: Figures 4-5

Subspecies B: Figures 6-7

Subspecies C: Figures 8-9

Subspecies D: Figures 10-11

Subspecies E: Figures 12-13

Species 2: Figures 17-19

Frictional Mechanism subspecies:

Subspecies a: Figure 20

Subspecies b: Figure 21.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species and subspecies for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

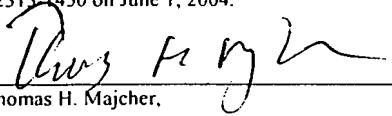
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO

Henry Bennett  
Supervisory Patent Examiner  
Group 3700

**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop Response, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 1, 2004.

  
Thomas H. Majcher,

Reg. No. 31,119

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appl. No.	:	09/897,295	Confirmation No.: 1994
Applicant	:	William J. Boyle et al.	
Filed	:	June 29, 2001	
Art Unit	:	3743	
Examiner	:	Odland, Kathryn P.	
Title	:	DELIVERY AND RECOVERY SHEATHS FOR MEDICAL DEVICES	
Docket No.:	:	ACS 56001 (2636P)	June 1, 2004
Customer No.	:	24201	Los Angeles, California

**RESPONSE TO ELECTION OF SPECIES REQUIREMENT**

Mail Stop Response  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This Response to the Election of Species Requirement is made to the Office Action of April 29, 2004, for which a response is due on June 1, 2004.

AMENDMENTS TO THE CLAIMS:

The listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

1. (Original) A restraining device for maintaining a self-expanding medical device on a delivery catheter, comprising:

a restraining sheath having an expandable housing portion adapted to receive and maintain the self-expanding medical device in a collapsed condition on the delivery catheter.

2. (Original) The restraining device of claim 1, wherein:

the expandable housing portion is adapted to expand between a contracted position and an expanded position, the housing portion having sufficient column strength to maintain the self-expanding medical device in its collapsed condition on its delivery catheter.

3. (Currently Amended) The restraining device of claim 2, wherein:

the expandable housing portion is made primarily from an elastic material which is stretchable between the contracted position and expanded position and includes at least one reinforcing reinforcing member associated therewith for providing additional column strength to the housing portion.

4. (Currently Amended) The restraining device of claim 3, further including:

a plurality of reinforcing reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion.

5. (Currently Amended) The restraining device of claim 4, wherein:  
the reinforcing reinforcing members extend substantially along the length of the expandable housing portion but do not interfere with the expansion of the elastic material.
6. (Currently Amended) The restraining device of claim 5, wherein:  
the reinforcing reinforcing members are elongated bar-like members made from a material having high stiffness.
7. (Original) The restraining device of claim 3, wherein:  
the elastic material is selected from a group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAK.
8. (Currently Amended) The restraining device of claim 4, wherein:  
the reinforcing reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.
9. (Currently Amended) The restraining device of claim 8, wherein:  
the reinforcing reinforcing members are loaded with a material having high radiopacity.
10. (Currently Amended) The restraining device of claim 1, wherein:  
the expandable housing portion is made from a substantially tubular-shaped material which is highly elastic and includes a plurality of [reinforcing] reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion.

11. (Currently Amended) The restraining device of claim 4, wherein:  
the reinforcing reinforcing members are disposed within the elastic material forming the expandable housing portion.
12. (Currently Amended) The restraining device of claim 4, wherein:  
the reinforcing reinforcing members are attached to the surface of the expandable housing portion.
13. (Currently Amended) The restraining device of claim 4, wherein:  
each reinforcing reinforcing member is disposed along the expandable housing portion to provide additional column strength to the housing portion but does not interfere with the expansion of the housing portion.
14. (Withdrawn) The restraining device of claim 2, further including:  
coil spring associated with the expandable housing portion which provides column strength to the housing portion and is expandable from the contracted position to the expanded position with the elastic material which forms the housing portion.
15. (Withdrawn) The restraining device of claim 14, wherein:  
the coils of the coil spring extend longitudinally along the length of the expandable housing portion.
16. (Withdrawn) The restraining device of claim 14, wherein:  
the coil spring is made from a material selected from a group including nickel-titanium, spring steel and highly flexible plastic.

17. (Withdrawn) The restraining device of claim 2, further including:  
a ring member disposed near the distal tip of the expandable housing portion.
18. (Withdrawn) The restraining device of claim 17, wherein:  
the ring member has a plurality of undulations and is expandable with the elastic material which forms the housing portion.
19. (Withdrawn) The restraining device of claim 18, wherein:  
the ring member is made from a material selected from a group including nickel-titanium, spring steel and highly flexible plastic.
20. (Original) The restraining device of claim 2, wherein:  
the expandable housing portion includes a low expansion section with at least one expansion member disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position.
21. (Original) The restraining device of claim 2, wherein:  
the expandable housing portion includes a plurality of low expansion sections and a plurality of expansion members disposed between low expansion sections.
22. (Original) The restraining device of claim 21, wherein:  
the low expansion sections are made from a material loaded with a material having high radiopacity.

23. (Original) The restraining device of claim 21, wherein:  
the expansion members are made from an elastic material selected from a group which includes polyurethane, silicone, polyisoprene and lower durometer PEBA.
24. (Original) The restraining device of claim 23, wherein:  
the low expansion sections are made from a material selected from a group including cross-linked HDPE, polyolefin and polyamide.
25. (Original) The restraining device of claim 21, wherein:  
the expansion members extend longitudinally along the length of the expandable housing portion.
26. (Original) The restraining device of claim 25, wherein:  
the expansion members include means for preventing the low expansion sections from tearing as the expandable housing portion expands from the contracted position to the expanded position.
27. (Withdrawn) The restraining device of claim 2, wherein:  
the expandable housing portion includes a distal tip section made from highly elastic material which is expandable and contractable between a contracted position and expanded position.
28. (Withdrawn) The restraining device of claim 27, wherein:  
the distal tip section is made from a more elastic material than the remaining portion of the expandable housing portion.

29. (Withdrawn) The restraining device of claim 28, further including:  
an expandable ring member associated with the distal tip section which is expandable between the contracted position and expanded position and is normally biased to the contracted position.
30. (Withdrawn) The restraining device of claim 29, wherein:  
the ring member is encapsulated within the material forming the distal tip section.
31. (Withdrawn) The restraining device of claim 29, wherein:  
the ring member is attached to the outer surface of the distal tip section.
32. (Withdrawn) The restraining device of claim 29, wherein:  
the ring member is made from materials selected from a group including nickel-titanium, stainless steel and highly elastic plastic.
33. (Withdrawn) A recovery device for retrieving from a body vessel a deployed embolic filtering device which includes an expandable filter basket mounted on a guide wire, the recovery device comprising:  
a recovery sheath having a lumen extending therethrough which is coaxially mounted on the guide wire of the filtering device, the recovery sheath having a distal end which is adapted to contact the filter basket to collapse the filter basket; and  
an inner recovery tip coaxially mounted on the guide wire, a portion of the inner recovery tip disposed within the lumen of the recovery sheath and a distal portion of the inner recovery tip extending distally from the distal tip of the recovery sheath as the recovery sheath and inner recovery tip move simultaneously along the guide wire.

34. (Withdrawn) The recovery device of claim 33, wherein:  
the inner recovery tip is slidable within the lumen of the recovery sheath after a certain amount of force is applied to the inner recovery tip.
35. (Withdrawn) The recovery device of claim 33, wherein:  
the inner recovery tip engages the inner surface of the lumen of the recovery sheath to maintain a frictional fit therebetween which is overcome upon application of a certain external force to the inner recovery tip.
36. (Withdrawn) The recovery device of claim 33, wherein:  
the inner recovery tip is in contact with the recovery sheath to maintain a frictional fit therebetween.
37. (Withdrawn) The recovery device of claim 33, wherein:  
the lumen of the recovery sheath defines a surface which contacts the surface of the inner recovery tip to maintain a frictional fit therebetween.
38. (Withdrawn) The recovery device of claim 37, further including:  
a mechanism for enhancing the frictional fit between the inner recovery tip and the recovery sheath.
39. (Withdrawn) The recovery device of claim 38, wherein:  
the mechanism includes a plurality of rib-like projections disposed on the surface of the recovery sheath which contact a plurality of rib-like projections on the surface of the inner recovery tip.

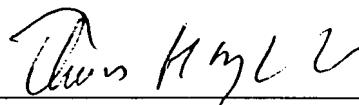
40. (Withdrawn) The recovery device of claim 39, wherein:  
the ribs of the recovery sheath are maintained in an interconnected  
relationship with the ribs of the inner recovery tip until a certain amount of force is  
applied to the inner recovery tip which causes the inner recovery tip to move within the  
lumen of the recovery sheath.

RESPONSE

Pursuant to the Election of Species Requirement of April 29, 2004 received in the above-referenced patent application, Applicants elect the Invention directed to Species I of FIGS. 1-3 and 14-16, and the expandable housing Subspecies A of FIGS. 4 and 5. Currently, original claims 1-13 and 20-26 are readable on this Species and Subspecies. In view of the Election of Species Requirement, Applicants have withdrawn claims 14-19 and 27-40 for consideration at this time. Claims 3-6 and 8-13 have been amended to correct the spelling of the word "reenforcing" to "reinforcing."

Respectfully submitted,

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,295	06/29/2001	William J. Boyle	ACS-56001 (26361)	1994

THM 24201 7590 08/27/2004

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FULWIDER PATTON LEE & UTECHT  
LOS ANGELES

EXAMINER

ODLAND, KATHRYN P

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 08/27/2004

*Response due November 27, 2004*

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/897,295	BOYLE ET AL.
	Examiner	Art Unit
	Kathryn Odland	3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 14 June 2004.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) 14-19 and 27-40 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-13 and 20-26 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/01, 3/1, 8/03.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Election/Restrictions***

1. Applicant's election without traverse of Species I in the reply filed on June 14, 2004 is acknowledged. Claims 1-13 and 20-26 are under consideration and claims 14-19 and 27-40 are withdrawn from consideration.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Hopkins et al. in US Patent No. 6,544,279.

Regarding claim 1, Hopkins et al. disclose a restraining device for maintaining a self-expanding medical device on a delivery catheter having a restraining sheath (584) having an expandable housing portion (594) adapted to receive and maintain the self-expanding medical device (588 and associated components) in a collapsed condition on the delivery catheter, as recited in column 23 and seen in figures 23A-23B.

Regarding claim 2, Hopkins et al. disclose that as applied to claim 1, as well as an expandable housing portion (594) that is adapted to expand between a contracted position and an expanded position, the housing portion having sufficient column strength to maintain

the self-expanding medical device in its collapsed condition on its delivery catheter, as recited in column 23 and seen in figures 23A-23B.

Regarding claim 20, Hopkins et al. disclose that as applied to claim 2, as well as an expandable housing portion (594) that includes a low expansion section with at least one expansion member (such as 590) disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position. "Low expansion section" is considered a relative phrase and a basis for comparison has not been provided.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 3-13 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hopkins et al. in US Patent No. 6,544,279 in view of Cryer et al. in US Patent No. 6,290,710.

Regarding claim 3, Hopkins et al. disclose that as applied to claim 2, as well as an expandable housing portion (594) that is made primarily from an elastic material, which is stretchable between the contracted position and expanded position. However, Hopkins et al. do not explicitly recite at least one reinforcing member associated therewith for providing additional column strength to the housing portion. On the other hand, it would be obvious to one with ordinary skill in the art to incorporate reinforcing members. For example, Cryer et al. teach reinforcement in column 8, lines 35-45. Thus, it would be within the scope of the invention and obvious to one with ordinary skill in the art to incorporate reinforcement members in the expandable housing of Hopkins et al. for the purpose of controlling the expansion/rigidity. It is known to combine different materials to achieve different strengths and expansion ability.

Regarding claim 4, Hopkins et al. as modified disclose that as applied to claim 2, as well as a plurality of reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion is within the scope of this modification and would be obvious to one with ordinary skill in the art.

Regarding claim 5, Hopkins et al. as modified disclose that as applied to claim 4, as well as reinforcing members that extend substantially along the length of the expandable housing portion but do not interfere with the expansion of the elastic material is within the scope of this modification and would be obvious to one with ordinary skill in the art.

Regarding claim 6, Hopkins et al. as modified disclose that as applied to claim 5 as well as reinforcing members (braids) that are elongated bar-like members made from a material having high stiffness, as recited in column 8, lines 35-45.

Regarding claims 7 and 23, Hopkins et al. as modified disclose that as applied to claims 3 and 21 as well as Cryer et al. further teach an elastic material that is selected from a group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAX, as recited in column 8, lines 35-45.

Regarding claim 8, Hopkins et al. as modified disclose that as applied to claim 4 as well as Cryer et al. further teach a reinforcing member that is made from a material selected from a group including stainless steel, polymeric material, and nitinol, as recited in column 8, lines 35-45.

Regarding claims 9 and 22, Hopkins et al. as modified disclose that as applied to claims 8 and 21 as well as radiopacity material (598). It would be further within the scope of the modification to have the reinforcing members loaded with a material having high radiopacity.

Regarding claim 10, Hopkins et al. as disclose that as applied to claim 1 as well as an expandable housing portion that is made from a substantially tubular-shaped material that is highly elastic. However, Hopkins et al. do not explicitly recite a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength

to the housing portion. On the other hand, it would be obvious to one with ordinary skill in the art to incorporate reinforcing members. For example, Cryer et al. teach reinforcement in column 8, lines 35-45. Thus, it would be within the scope of the invention and obvious to one with ordinary skill in the art to incorporate reinforcement members in the expandable housing of Hopkins et al. for the purpose of controlling the expansion/rigidity. It is known to combine different materials to achieve different strengths and expansion ability.

Regarding claims 11-13, Hopkins et al. as disclose that as applied to claim 4. However the following claims disclose location options for the reinforcing members. Since no particular location has been deemed critical they can be considered equivalents. Thus, it would be within the scope of the modification to have the reinforcing members disposed within the elastic material forming the expandable housing portion, attached to the surface of the expandable housing portion, and/or disposed along the expandable housing portion.

Regarding claim 21, Hopkins et al. as disclose that as applied to claim 2. However, Hopkins et al. do not explicitly recite a plurality of low expansion sections and a plurality of expansion members disposed between low expansion sections. On the other hand, it would be obvious to one with ordinary skill in the art to incorporate reinforcing members. For example, Cryer et al. teach reinforcement in column 8, lines 35-45. Thus, it would be within the scope of the invention and obvious to one with ordinary skill in the art to incorporate reinforcement members in the expandable housing of Hopkins et al. for the purpose of controlling the expansion/rigidity. It is known to combine different materials to achieve different strengths and expansion ability. Further, to have the expansion members

disposed between the low expansion sections would further be obvious to one with ordinary skill in the art.

Regarding claim 24, Hopkins et al. as modified disclose that as applied to claim 23 as well as Cryer et al. teach low expansion sections that are made from a material selected from a group including cross-linked HDPE, polyolefin and polyamide, as recited in column 8, lines 35-45.

Regarding claim 25, Hopkins et al. as modified disclose that as applied to claim 21. Further, this modification would yield expansion members that extend longitudinally along the length of the expandable housing portion.

Regarding claim 26, Hopkins et al. as modified disclose that as applied to claim 25. Further, this modification would yield expansion members that include means for preventing the low expansion sections from tearing as the expandable housing portion expands from the contracted position to the expanded position.

### ***Conclusion***

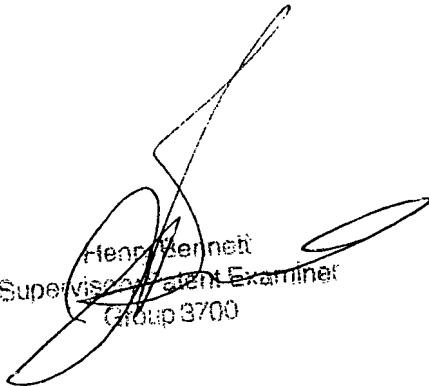
7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US 2004/0044359; US 2002/0095170; US 2002/0058963; US 2002/0183781; US 2002/0107541; US Patent No. 6,685,722; US Patent No. 6,679,902; US Patent No. 6,383,206; US Patent No. 6,221,006; US Patent No. 6,171,327; and US Patent No. 5,766,203.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



Henry Bennett  
Supervisory Patent Examiner  
Group 3700





#2

PTO/SB/08A (10-96)

Exhibit 6 for Form 1449AFTO

## **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

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<i>Complete if Known</i>	
Application Number	09/897,295
Filing Date	June 29, 2001
First Named Inventor	William J. Boyle
Group Art Unit	3732
Examiner Name	Unassigned
Attorney Docket Number	ACS-56001

## U.S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

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**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

CITATION INFORMATION - WORKS CITED ON THE DOCUMENTS		
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published

Examiner Signature	Kathryn Odland	Date Considered	8/23/04
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Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

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Complete if Known

Serial

Application Number	09/897,296
Filing Date	June 29, 2001
First Named Inventor	William J. Boyle, et al
Art Unit	3732
Examiner Name	Unassigned

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## U.S. PATENT DOCUMENTS

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Date Considered

8/23/04

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<b>Notice of References Cited</b>	Application/Control No.	Applicant(s)/Patent Under Reexamination BOYLE ET AL.	
	Examiner Kathryn Odland	Art Unit 3743	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-6,544,279	04-2003	Hopkins et al.	606/200
	B	US-6,290,710	09-2001	Cryer et al.	606/200
	C	US-2004/0044359	03-2004	Renati et al.	606/200
	D	US-2002/0095170	07-2002	Krolik et al.	606/200
	E	US-2002/0058963	05-2002	Vale et al.	606/200
	F	US-2002/0183781	12-2002	Casey et al.	606/198
	G	US-2002/0107541	08-2002	Vale et al.	606/200
	H	US-6,685,722	02-2004	Rosenbluth et al.	606/200
	I	US-6,679,902	01-2004	Boyle et al.	606/200
	J	US-6,383,206	05-2002	Gillick et al.	606/200
	K	US-6,221,006	04-2001	Dubrul et al.	600/159
	L	US-6,171,327	01-2001	Daniel et al.	606/200
	M	US-5,766,203	06-1998	Imran et al.	623/1.11

**FOREIGN PATENT DOCUMENTS**

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	P					
	Q					
	R					
	S					
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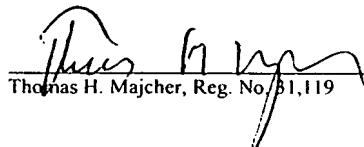
**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 29, 2004.

  
Thomas H. Majcher, Reg. No. 31,119

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	: 09/897,295	Confirmation No. 1994
Applicant	: William J. Boyle et al.	
Filed	: June 29, 2001	
Art Unit	: 3743	
Examiner	: Odland, Kathryn P.	
Title	: DELIVERY AND RECOVERY SHEATHS FOR MEDICAL DEVICES	
Docket No.:	: ACSES 56001 (2636P)	Los Angeles, California
Customer No.	: 24201	November 29, 2004

Mail Stop AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

AMENDMENT

Dear Sir:

This Amendment is responsive to the Office Action of August 27, 2004, the response for which is due November 29, 2004.

Claims start on page 2.

Remarks start on page 9.

AMENDMENTS TO THE CLAIMS:

The listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

1-2. (Canceled)

3. (Currently Amended) The A restraining device of claim 2 for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath having an expandable housing portion adapted to receive and maintain the self-expanding medical device in a collapsed condition on the delivery device, the expandable housing portion being adapted to expand between a contracted position and an expanded position, the housing portion having sufficient column strength to maintain the self-expanding medical device in its collapsed condition on its delivery device, wherein:

the expandable housing portion is made primarily from an elastic material which is stretchable between the contracted position and expanded position and includes at least one reinforcing member associated therewith for providing additional column strength to the housing portion.

4. (Previously Presented) The restraining device of claim 3, further including:

a plurality of reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion.

5. (Previously Presented) The restraining device of claim 4, wherein:

the reinforcing members extend substantially along the length of the expandable housing portion but do not interfere with the expansion of the elastic material.

6. (Previously Presented) The restraining device of claim 5, wherein:  
the reinforcing members are elongated bar-like members made from a material having high stiffness.
7. (Original) The restraining device of claim 3, wherein:  
the elastic material is selected from a group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAK.
8. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.
9. (Previously Presented) The restraining device of claim 8, wherein:  
the reinforcing members are loaded with a material having high radiopacity.
10. (Currently Amended) The restraining device of claim [[1]] 3, wherein:  
the expandable housing portion is made from a substantially tubular-shaped material which is highly elastic and includes a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion.
11. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing members are disposed within the elastic material forming the expandable housing portion.
12. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing members are attached to the surface of the expandable housing portion.

13. (Previously Presented) The restraining device of claim 4, wherein:  
each reinforcing member is disposed along the expandable housing portion to provide additional column strength to the housing portion but does not interfere with the expansion of the housing portion.
14. (Withdrawn) The restraining device of claim 2, further including:  
coil spring associated with the expandable housing portion which provides column strength to the housing portion and is expandable from the contracted position to the expanded position with the elastic material which forms the housing portion.
15. (Withdrawn) The restraining device of claim 14, wherein:  
the coils of the coil spring extend longitudinally along the length of the expandable housing portion.
16. (Withdrawn) The restraining device of claim 14, wherein:  
the coil spring is made from a material selected from a group including nickel-titanium, spring steel and highly flexible plastic.
17. (Withdrawn) The restraining device of claim 2, further including:  
a ring member disposed near the distal tip of the expandable housing portion.
18. (Withdrawn) The restraining device of claim 17, wherein:  
the ring member has a plurality of undulations and is expandable with the elastic material which forms the housing portion.
19. (Withdrawn) The restraining device of claim 18, wherein:  
the ring member is made from a material selected from a group including nickel-titanium, spring steel and highly flexible plastic.

20. (Currently Amended) The restraining device of claim [[2]] 3, wherein:  
the expandable housing portion includes a low expansion section with at least one expansion member disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position.
21. (Currently Amended) The restraining device of claim [[2]] 3, wherein:  
the expandable housing portion includes a plurality of low expansion sections and a plurality of expansion members disposed between low expansion sections.
22. (Original) The restraining device of claim 21, wherein:  
the low expansion sections are made from a material loaded with a material having high radiopacity.
23. (Original) The restraining device of claim 21, wherein:  
the expansion members are made from an elastic material selected from a group which includes polyurethane, silicone, polyisoprene and lower durometer PEBAK.
24. (Original) The restraining device of claim 23, wherein:  
the low expansion sections are made from a material selected from a group including cross-linked HDPE, polyolefin and polyamide.
25. (Original) The restraining device of claim 21, wherein:  
the expansion members extend longitudinally along the length of the expandable housing portion.
26. (Original) The restraining device of claim 25, wherein:  
the expansion members include means for preventing the low expansion sections from tearing as the expandable housing portion expands from the contracted position to the expanded position.

27. (Withdrawn) The restraining device of claim 2, wherein:  
the expandable housing portion includes a distal tip section made from highly elastic material which is expandable and contractable between a contracted position and expanded position.
28. (Withdrawn) The restraining device of claim 27, wherein:  
the distal tip section is made from a more elastic material than the remaining portion of the expandable housing portion.
29. (Withdrawn) The restraining device of claim 28, further including:  
an expandable ring member associated with the distal tip section which is expandable between the contracted position and expanded position and is normally biased to the contracted position.
30. (Withdrawn) The restraining device of claim 29, wherein:  
the ring member is encapsulated within the material forming the distal tip section.
31. (Withdrawn) The restraining device of claim 29, wherein:  
the ring member is attached to the outer surface of the distal tip section.
32. (Withdrawn) The restraining device of claim 29, wherein:  
the ring member is made from materials selected from a group including nickel-titanium, stainless steel and highly elastic plastic.

33-40. (Canceled)

41. (New) A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath having an expandable housing portion adapted to expand between a contracted position and an expanded position and to maintain the self-expanding medical device in a collapsed condition on the delivery device, and a reinforcing member associated with the expandable housing portion to cooperatively provide sufficient strength to the expandable housing portion to maintain the self-expanding medical device in its collapsed condition on its delivery device without the reinforcing member interfering with the ability of the expandable housing portion to move between the contracted and expanded positions.

42. (New) The restraining device of claim 41, further including:

a plurality of reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion but which do not interfere with the ability of the expandable housing to move between the contracted and expanded positions.

43. (New) The restraining device of claim 41, wherein:

the reinforcing member is embedded in the wall which forms the expandable housing portion.

44. (New) The restraining device of claim 41, wherein:

the reinforcing member is an elongated bar-like member made from a material having a stiffness higher than the stiffness of the material used to form the expandable housing portion.

45. (New) The restraining device of claim 41, wherein:

the expandable housing portion is made from an elastic material selected from a group of materials which includes silicone, polyurethane, polyisoprene, and low durometer PEBAK.

46. (New) The restraining device of claim 41, wherein:  
the reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.
47. (New) The restraining device of claim 41, wherein:  
the reinforcing member is loaded with a material having high radiopacity.
48. (New) The restraining device of claim 41, wherein:  
the expandable housing portion is made from a substantially tubular-shaped material which is highly elastic and includes a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion.
49. (New) The restraining device of claim 41, wherein:  
the reinforcing member is molded within the material used to form the expandable housing portion.
50. (New) The restraining device of claim 41, wherein:  
the reinforcing member is attached to the surface of the expandable housing portion.
51. (New) The restraining device of claim 41, wherein:  
the reinforcing member helps to bias the expandable housing portion in the contracted position.

REMARKS

This Amendment is in response to the Office Action dated August 27, 2004. Claims 1-40 were pending in this application. Previously, claims 14-19 and 27-40 were withdrawn from consideration in view of an earlier election of species requirement. By this Amendment, Applicants have canceled claims 1, 2 and 33-40 without prejudice. Claim 3 has been rewritten in independent form and amended to recite a "delivery device" rather than a "delivery catheter" in the preamble. Claims 10, 20 and 21 have been amended to depend from claim 3. New claims 41-51 are being presented. Favorable reconsideration of all the pending claims is respectfully requested.

The Examiner rejected claims 1, 2 and 20 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,544,279 to Hopkins et al. (the "Hopkins patent"). In view of Applicants' cancellation of claims 1 and 2 without prejudice and the amendment of claim 20 to depend from claim 3, this rejection should now be withdrawn by the Examiner.

The Examiner has rejected claims 3-13 and 21-26 under 35 U.S.C. § 103(a) as being unpatentable over the Hopkins patent in view of U.S. Patent No. 6290,710 to Cryer et al. (the "Cryer patent"). Applicants respectfully submit that the Cryer patent and the present application were, at the time the presently claimed invention was made, each either owned by, or subject to, an obligation of assignment to Advanced Cardiovascular Systems, Inc. Applicants direct the Examiner's attention to the recorded assignment of the present invention to Advanced Cardiovascular Systems, Inc., which is recorded at Reel/Frame 011971/0220 on June 29, 2001. The present application was filed after the November 22, 1999 effective date of change to 35 U.S.C. § 103(c) which disqualifies § 102(e) prior art from consideration under § 103 if the subject matter of the reference and the claimed invention were commonly owned at the time the claimed invention was made. The Cryer patent constitutes a § 102(e) reference and has been cited in the current Office Action as a § 103(a) reference. Applicants have made herein a statement that the Cryer patent and the present application were, at the time the invention was made, each

either owned by or subject to an obligation of assignment to the same company. In view of this statement of common ownership, Applicants respectfully asserts that the Cryer patent is not a valid 35 U.S.C. § 103 (a) reference and traverse the current rejections. MPEP 706.02 (l) (2).

Applicants respectfully request the Examiner to withdraw the U.S.C. § 103(a) rejection as applied to claims 3-13 and 21-26 since all rejections are based on the combination of the Cryer patent with the Hopkins patent. Without the teachings of the Cryer patent, the combination of the other references simply fails to achieve the claimed structure of the pending claims.

In view of the foregoing, it is respectfully urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above amendments and remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By:   
Thomas H. Majcher  
Registration No. 31,119

THM:kh

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UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,295	06/29/2001	William J. Boyle	ACS-56001 (26361)	1994
24201	7590	02/24/2005	EXAMINER	
FULWIDER PATTON LEE & UTECHT, LLP HOWARD HUGHES CENTER 6060 CENTER DRIVE TENTH FLOOR LOS ANGELES, CA 90045			RAGONESE, ANDREA M	
		ART UNIT	PAPER NUMBER	
		3743		
DATE MAILED: 02/24/2005				

*THM*  
Response Due May 24, 2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/897,295	BOYLE ET AL.
	Examiner	Art Unit
	Andrea M. Ragonese	3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 02 December 2004.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 3-32 and 41-51 is/are pending in the application.
- 4a) Of the above claim(s) 14-19 and 27-32 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 3-13,20-26 and 41-51 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Amendment*

1. The amendment filed on December 2, 2004 has been entered. Examiner acknowledges that **claims 3, 10, 20 and 21** have been amended, **claims 1-2** have been canceled and **claims 41-51** have been added. Subsequently, **claims 3-13, 20-26** and **41-51** under consideration, while **claims 14-19** and **27-32** have been withdrawn from further consideration.

### *Response to Arguments*

2. Applicant's arguments, see pages 9-10, filed December 2, 2004, with respect to the rejection of **claims 3-13** and **21-26** under 35 U.S.C. § 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, new grounds of rejection are made hereinafter.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claims 43 and 51** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, **claim 43** recites a "reinforcing member" that "is embedded in the wall which forms the expandable housing" and **claim**

51 recites a "reinforcing member" that "helps to bias the expandable housing in the contracted position." Both of these claim limitations were not present in the original disclosure and therefore, are considered new matter, which cannot be entered in an amendment.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. **Claims 3-13, 20-26 and 41-51** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hopkins et al. (US 6,544,279) in view of Amplatz (US 6,123,715).

Regarding **claims 3 and 41**, Hopkins et al. discloses a restraining device for maintaining a self-expanding medical device on a delivery device, including an expandable housing portion (594) that is made primarily from an elastic material, which

is stretchable between the contracted position and expanded position. However, Hopkins et al. do not explicitly recite at least one reinforcing member associated therewith for providing additional column strength to the housing portion. On the other hand, it would be obvious to one with ordinary skill in the art to incorporate reinforcing members. For example, Amplatz teaches the use of reinforcing members for providing additional strength to a guiding catheter (column 3, lines 40-49). Thus, it would be within the scope of the invention and obvious to one with ordinary skill in the art to incorporate reinforcement members in the expandable housing of Hopkins et al. for the purpose of controlling the expansion/rigidity. It is known to combine different materials to achieve different strengths and expansion ability.

Regarding **claims 4 and 42**, Hopkins et al. as modified discloses that as applied to **claims 3 and 41**, as well as a plurality of reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion is within the scope of this modification and would be obvious to one with ordinary skill in the art.

Regarding **claim 5**, Hopkins et al. as modified discloses that as applied to **claim 4**, as well as reinforcing members that extend substantially along the length of the expandable housing portion but do not interfere with the expansion of the elastic material is within the scope of this modification and would be obvious to one with ordinary skill in the art.

Regarding **claims 6 and 44**, Hopkins et al. as modified discloses that as applied to **claims 5 and 41** as well as reinforcing members (braids) that are elongated bar-like members made from a material having high stiffness (column 4, lines 11-24).

Regarding **claims 7 and 45**, Hopkins et al. as modified discloses that as applied to **claims 3 and 41** as well as an elastic material that is selected from a group of materials, which includes silicone, polyurethane, polyisoprene and lower durometer PEBAX.

Regarding **claims 8 and 46**, Hopkins et al. as modified discloses that as applied to **claims 4 and 41** as well as Amplatz further teaches a reinforcing member that is made from a material selected from a group including stainless steel, polymeric material, and Nitinol.

Regarding **claims 9 and 47**, Hopkins et al. as modified discloses that as applied to **claims 8 and 41** as well as radiopacity material (598). It would be further within the scope of the modification to have the reinforcing members loaded with a material having high radiopacity.

Regarding **claims 10 and 48**, Hopkins et al. as modified discloses that as applied to **claims 3 and 41** as well as an expandable housing portion that is made from a substantially tubular-shaped material that is highly elastic. However, Hopkins et al. do not explicitly recite a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion. On the other hand, it would be obvious to one with ordinary skill in the art to incorporate reinforcing members. For example, Amplatz teaches the use of reinforcing members for providing

additional strength to a guiding catheter (column 3, lines 40-49). Thus, it would be within the scope of the invention and obvious to one with ordinary skill in the art to incorporate reinforcement members in the expandable housing of Hopkins et al. for the purpose of controlling the expansion/rigidity. It is known to combine different materials to achieve different strengths and expansion ability.

Regarding **claims 11-13, 43 and 48-50**, Hopkins et al. as modified discloses that as applied to **claims 4 and 41**. However, the following claims disclose location options for the reinforcing members. Since no particular location has been deemed critical, they can be considered equivalents. Thus, it would be within the scope of the modification to have the reinforcing members disposed within the elastic material forming the expandable housing portion, attached to the surface of the expandable housing portion, and/or disposed along the expandable housing portion.

Regarding **claim 20**, Hopkins et al. as modified discloses that as applied to **claim 3**, as well as an expandable housing portion (594) that includes a low expansion section with at least one expansion member (such as 590) disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position. "Low expansion section" is considered a relative phrase and a basis for comparison has not been provided.

Regarding **claim 21**, Hopkins et al. as modified discloses that as applied to **claim 3**. However, Hopkins et al. do not explicitly recite a plurality of low expansion sections and a plurality of expansion members disposed between low expansion sections. On the other hand, it would be obvious to one with ordinary skill in the art to incorporate

reinforcing members. For example, Amplatz teaches the use of reinforcing members for providing additional strength to a guiding catheter (column 3, lines 40-49). Thus, it would be within the scope of the invention and obvious to one with ordinary skill in the art to incorporate reinforcement members in the expandable housing of Hopkins et al. for the purpose of controlling the expansion/rigidity. It is known to combine different materials to achieve different strengths and expansion ability. Further, to have the expansion members disposed between the low expansion sections would further be obvious to one with ordinary skill in the art.

Regarding **claim 22**, Hopkins et al. as modified discloses that as applied to **claim 21** as well as radiopacity material (598). It would be further within the scope of the modification to have the reinforcing members loaded with a material having high radiopacity.

Regarding **claim 23**, Hopkins et al. as modified discloses that as applied to **claim 21** as well as an elastic material that is selected from a group of materials, which includes silicone, polyurethane, polyisoprene and lower durometer PEBAK.

Regarding **claim 24**, Hopkins et al. as modified discloses that as applied to **claim 23** as well as low expansion sections that are made from a material selected from a group including cross-linked HDPE, polyolefin and polyamide.

Regarding **claim 25**, Hopkins et al. as modified discloses that as applied to **claim 21**. Further, this modification would yield expansion members that extend longitudinally along the length of the expandable housing portion.

Regarding **claim 26**, Hopkins et al. as modified discloses that as applied to **claim 25**. Further, this modification would yield expansion members that include means for preventing the low expansion sections from tearing as the expandable housing portion expands from the contracted position to the expanded position.

Regarding **claim 51**, Hopkins et al. as modified discloses that as applied to **claim 41** as well as teaching reinforcing members that are fully capable of helping to bias the expandable housing portion in the contracted position.

### ***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese whose telephone number is 571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

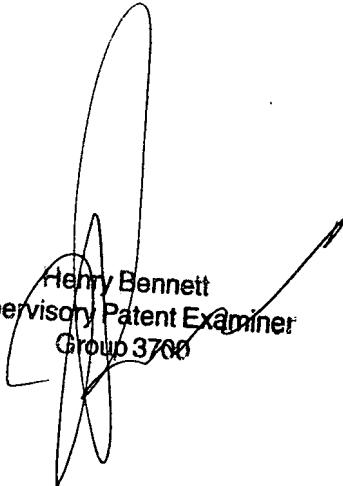
9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 09/897,295  
Art Unit: 3743

Page 9

AMR  
February 22, 2005



Henry Bennett  
Supervisory Patent Examiner  
Group 3700

<b>Notice of References Cited</b>	Application/Control No. 09/897,295	Applicant(s)/Patent Under Reexamination BOYLE ET AL.
	Examiner Andrea M. Ragonese	Art Unit 3743

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-6,123,715	09-2000	Amplatz, Curtis	606/200
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

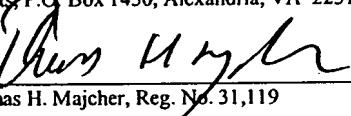
**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on May 20, 2005.

  
\_\_\_\_\_  
Thomas H. Majcher, Reg. No. 31,119

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 09/897,295  
Applicant : William J. Boyle et al.  
Filed : June 29, 2001  
Title : DELIVERY AND RECOVERY SHEATHS  
FOR MEDICAL DEVICES  
Art Unit : 3743  
Examiner : Ragonese, Andrea M.  
Docket No.: : ACSES 56001 (2636P) Los Angeles, California  
Customer No. : 24201 May 20, 2005

MAIL STOP AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

AMENDMENT

Dear Sir:

This Amendment is responsive to the Office Action of February 24, 2005, the response for which is due May 24, 2005.

Claims start on page 2.

Remarks start on page 9.

AMENDMENTS TO THE CLAIMS:

The below listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1-2. (Cancelled)

3. (Currently Amended) A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath having an expandable housing portion adapted to receive and maintain the self-expanding medical device in a collapsed condition on the delivery device, the expandable housing portion being adapted to expand between a contracted position and an expanded position, the housing portion having sufficient column strength to maintain the self-expanding medical device in its collapsed condition on its delivery device, wherein:

the expandable housing portion is made primarily from an elastic material which is stretchable between the contracted position and expanded position and includes at least one reinforcing member associated therewith ~~for providing which provides~~ additional column strength to the housing portion but does not interfere with the expansion of the housing portion.

4. (Previously Presented) The restraining device of claim 3, further including:

a plurality of reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion.

5. (Previously Presented) The restraining device of claim 4, wherein:

the reinforcing members extend substantially along the length of the expandable housing portion but do not interfere with the expansion of the elastic material.

6. (Previously Presented) The restraining device of claim 5, wherein:

the reinforcing members are elongated bar-like members made from a material having high stiffness.

7. (Original) The restraining device of claim 3, wherein:  
the elastic material is selected from a group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAx.
8. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.
9. (Previously Presented) The restraining device of claim 8, wherein:  
the reinforcing members are loaded with a material having high radiopacity.
10. (Previously Presented) The restraining device of claim 3, wherein:  
the expandable housing portion is made from a substantially tubular-shaped material which is highly elastic and includes a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion.
11. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing members are disposed within the elastic material forming the expandable housing portion.
12. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing members are attached to the surface of the expandable housing portion.
13. (Previously Presented) The restraining device of claim 4, wherein:  
each reinforcing member is disposed along the expandable housing portion to provide additional column strength to the housing portion but does not interfere with the expansion of the housing portion.
14. (Withdrawn) The restraining device of claim 2, further including:  
coil spring associated with the expandable housing portion which provides column strength to the housing portion and is expandable from the contracted position to the expanded position with the elastic material which forms the housing portion.

15. (Withdrawn) The restraining device of claim 14, wherein:  
the coils of the coil spring extend longitudinally along the length of the expandable housing portion.
16. (Withdrawn) The restraining device of claim 14, wherein:  
the coil spring is made from a material selected from a group including nickel-titanium, spring steel and highly flexible plastic.
17. (Withdrawn) The restraining device of claim 2, further including:  
a ring member disposed near the distal tip of the expandable housing portion.
18. (Withdrawn) The restraining device of claim 17, wherein:  
the ring member has a plurality of undulations and is expandable with the elastic material which forms the housing portion.
19. (Withdrawn) The restraining device of claim 18, wherein:  
the ring member is made from a material selected from a group including nickel-titanium, spring steel and highly flexible plastic.
20. (Previously Presented) The restraining device of claim 3, wherein:  
the expandable housing portion includes a low expansion section with at least one expansion member disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position.
21. (Previously Presented) The restraining device of claim 3, wherein:  
the expandable housing portion includes a plurality of low expansion sections and a plurality of expansion members disposed between low expansion sections.
22. (Original) The restraining device of claim 21, wherein:  
the low expansion sections are made from a material loaded with a material having high radiopacity.

23. (Original) The restraining device of claim 21, wherein:  
the expansion members are made from an elastic material selected from a group which includes polyurethane, silicone, polyisoprene and lower durometer PEBA.
24. (Original) The restraining device of claim 23, wherein:  
the low expansion sections are made from a material selected from a group including cross-linked HDPE, polyolefin and polyamide.
25. (Original) The restraining device of claim 21, wherein:  
the expansion members extend longitudinally along the length of the expandable housing portion.
26. (Original) The restraining device of claim 25, wherein:  
the expansion members include means for preventing the low expansion sections from tearing as the expandable housing portion expands from the contracted position to the expanded position.
27. (Withdrawn) The restraining device of claim 2, wherein:  
the expandable housing portion includes a distal tip section made from highly elastic material which is expandable and contractable between a contracted position and expanded position.
28. (Withdrawn) The restraining device of claim 27, wherein:  
the distal tip section is made from a more elastic material than the remaining portion of the expandable housing portion.
29. (Withdrawn) The restraining device of claim 28, further including:  
an expandable ring member associated with the distal tip section which is expandable between the contracted position and expanded position and is normally biased to the contracted position.

30. (Withdrawn) The restraining device of claim 29, wherein:  
the ring member is encapsulated within the material forming the distal tip section.
31. (Withdrawn) The restraining device of claim 29, wherein:  
the ring member is attached to the outer surface of the distal tip section.
32. (Withdrawn) The restraining device of claim 29, wherein:  
the ring member is made from materials selected from a group including nickel-titanium, stainless steel and highly elastic plastic.

33-40. (Canceled)

41. (Previously Presented) A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:  
a restraining sheath having an expandable housing portion adapted to expand between a contracted position and an expanded position and to maintain the self-expanding medical device in a collapsed condition on the delivery device, and a reinforcing member associated with the expandable housing portion to cooperatively provide sufficient strength to the expandable housing portion to maintain the self-expanding medical device in its collapsed condition on its delivery device without the reinforcing member interfering with the ability of the expandable housing portion to move between the contracted and expanded positions.
42. (Previously Presented) The restraining device of claim 41, further including:  
a plurality of reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion but which do not interfere with the ability of the expandable housing to move between the contracted and expanded positions.
43. (Withdrawn) The restraining device of claim 41, wherein:  
the reinforcing member is embedded in the wall which forms the expandable housing portion.

44. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is an elongated bar-like member made from a material having a stiffness higher than the stiffness of the material used to form the expandable housing portion.
45. (Previously Presented) The restraining device of claim 41, wherein:  
the expandable housing portion is made from an elastic material selected from a group of materials which includes silicone, polyurethane, polyisoprene, and low durometer PEBAX.
46. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.
47. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is loaded with a material having high radiopacity.
48. (Previously Presented) The restraining device of claim 41, wherein:  
the expandable housing portion is made from a substantially tubular-shaped material which is highly elastic and includes a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion.
49. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is molded within the material used to form the expandable housing portion.
50. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is attached to the surface of the expandable housing portion.
51. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member helps to bias the expandable housing portion in the contracted position.

filter basket, it will collapse back to its normally collapsed position as shown in Fig. 16. Accordingly, it is believed that the invention described in claim 51 is fully disclosed in the specification.

The Examiner has rejected claims 3-13 and 21-26 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,544,279 to Hopkins et al. (the "Hopkins patent") in view of U.S. Patent No. 6,123,715 to Amplatz (the "Amplatz patent"). Applicants strongly disagree with the Examiner's position that it would have been obvious to one skilled in the art to incorporate reinforcing members with the expandable housing of the Hopkins patent for the purpose of controlling the expansion/rigidity of the expandable housing. First, the Amplatz patent simply states that the use of tubular fabrics and tubular braids are well known in the fabric arts and that such fabrics have been used to reinforce the wall of a guiding catheter. However, conventional guiding catheters which utilize a tubular braid or tubular fabric do so in order to reinforce the catheter and prevent any expansion of the guiding catheter.

In the present claims, the reinforcing member provides additional column strength to the housing portion but does not interfere with the expansion of the housing portion. The tubular braid mentioned in the Amplatz patent does the very opposite, rather, and prevents any expansion. Therefore, the combination of the tubular braid with the housing described in the Hopkins patent would create a housing that would be reinforced, but would not expand. Accordingly, Applicants submit that the combination of the Hopkins patent with the Amplatz patent simply fails to create the structure recited in the present claims and would create a housing structure that is incapable of expanding. Applicants respectfully request the Examiner to withdraw the § 103 rejection which has been applied to all of the pending claims.

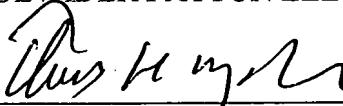
In view of the foregoing, it is respectfully urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above amendments and remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By:

  
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# UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,295	06/29/2001	William J. Boyle ACS	ACS-56001 (26361)	1994
24201	7590	09/29/2005	EXAMINER	
FULWIDER PATTON LEE & UTECHT, LLP HOWARD HUGHES CENTER 6060 CENTER DRIVE TENTH FLOOR LOS ANGELES, CA 90045			MITCHELL, TEENA KAY	
		ART UNIT	PAPER NUMBER	
		3743		
DATE MAILED: 09/29/2005				

THM  
Please find below and/or attached an Office communication concerning this application or proceeding.

## FINAL REJECTION

2 - MONTH RESPONSE DUE: November 29, 2005  
3 - MONTH RESPONSE DUE: December 29, 2005  
NOTICE OF APPEAL DUE:  
(6-MONTH PERIOD ENDS) March 29, 2006

Reb. to Shobek 10/14/05

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/897,295	BOYLE ET AL.
	Examiner	Art Unit
	Teena Mitchell	3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 25 May 2005.
- 2a) This action is FINAL.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 3-32 and 41-51 is/are pending in the application.
- 4a) Of the above claim(s) 14-19 and 27-32 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 3-13,20-26 and 41-51 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### ***Response to Arguments***

Applicant's arguments, see page 8, filed 5/25/05, with respect to 112, first paragraph have been fully considered and are persuasive. The 112 first paragraph rejection of claims 43 and 51 has been withdrawn.

Applicant's arguments filed 5/25/05 have been fully considered but they are not persuasive. Applicant argues that Amplatz tubular braid prevents any expansion; however, the reference of Amplatz teaches that "...the pitch of wire stands (i.e., the angle defined between the turns of the wire and the axis of the braid) and the pick of the fabric (i.e. the number of turns per unit length) may be adjusted as desired for a particular application. As such is taught by Amplatz one of ordinary skill in the art would based on the pitch and the pick of the fabric select such to provide expansion of the expandable housing. Furthermore, in order to provide additional support for the examiners rejection, the teachings of Kelley is provided in the rejection. Applicant argues that Amplatz teaches away from expansion but does not provide any reference to such in the Amplatz references. The braids provide flexibility (i.e., the ability to expand) to the tubular member, while providing reinforcement.

### ***Claim Rejections - 35 USC § 112***

**The following is a quotation of the first paragraph of 35 U.S.C. 112:**

**The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

**Claims 3-13, 20-26, 41, 42, and 44-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification provides support for the limitation of, "...does not interfere with the radial expansion of the housing portion..." however applicant is claiming "...the expansion of the housing portion...".**

***Claim Rejections - 35 USC § 103***

**The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

**(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.**

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.**

**Claims 3-13, 20-26, and 41-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hopkins et.al. (6,544,279) in view of Amplatz (6,123,715) and Kelley (6,517,765).**

Hopkins in a restraining device discloses a restraining sheath having an expandable housing portion (594) adapted to receive and maintain the self-expanding medical device (588) in a collapsed condition on the delivery device, the expandable

housing portion being adapted to expand between a contracted position (Fig. 23A) and an expanded position (Fig. 23B), the housing portion having sufficient column strength to maintain the self-expanding medical device (588) in its collapsed condition on its delivery device, wherein the expandable housing portion (594) is made primarily from an elastic material which is stretchable between the contracted position and expanded position.

The difference between Hopkins and claim 3 is a reinforcing member associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion of the housing portion.

Amplatz in an intravascular occlusion device teaches the use of tubular braids in medical devices providing reinforcing means to the wall of a guiding catheter, which may be adjusted as desired for a particular application by the pitch and pick of the fabric (Col. 3, lines 39-57). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the expandable housing portion of Hopkins to employ any well-known tubular braids doing so would have provided a means to reinforce the expandable housing portion. Further the teachings of Kelley teach the use of braids in varying braid pick counts vary the flexibility of the tubing (Col. 1, lines 40-67 and Col. 2, lines 1-15). Based on a standard dictionary definition of "flexible, Capable of being bent or flexed: Pliable. "pliable" meaning, easily bent or shaped: Malleable, capable of being shaped or formed. Therefore, based on the teachings of braids of Kelley, the tubular braids of Amplatz could be adjusted to allow for expansion of the

housing portion and therefore, would not interfere with the expansion of the housing portion, as one of ordinary skill in the art would know.

With respect to claim 4, Amplatz does not teach a plurality of reinforcing members. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have a plurality of reinforcing members, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

With respect to claim 5, Amplatz does not teach the reinforcing member extending substantially along the length of the expandable housing portion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the reinforcing member extending substantially along the length of the expandable housing portion, since it has been held that rearranging parts of an invention involves only routine skill in the art and applicant has not disclosed that having the reinforcing members extending substantially along the length of the expandable housing portion provides an advantage or solves a particular problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the reinforcing member positioned in any other arrangement of the housing portion because the housing portion would still be expandable. Therefore, it would have been an obvious matter of design consideration to modify Hopkin/Ampatz to obtain the invention as specified in claim 5.

With respect to claim 6, Amplatz teaches the reinforcing members are elongated bar-like members made from a material having a high stiffness (Col. 4, lines 11-65).

With respect to claim 7, Hopkins does not specifically disclose the elastic material selected from the group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAK. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the elastic material selected from the group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAK, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design consideration. Applicant has not disclosed that having the elastic member selected from the group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAK provides an advantage, is used for a particular purpose, or solves any stated problem. One of ordinary skill in the art, furthermore would have expected Applicant's invention to perform equally well with other materials which provide elastic properties because the housing portion would still be able to expand. Therefore, it would have been an obvious matter of design consideration to modify Hopkins/Amplatz to obtain the invention as specified in claim 7.

With respect to claim 8, note rejection of claim 7 above.

With respect to claim 9, Hopkins/Amplatz do not disclose/teach the reinforcing members loaded with a material having high radiopacity. However, Hopkins does disclose the use of radipaque bands (596, 598) providing a means so that positions of the bands relative to one another may be accurately determined. It would have been obvious to one of ordinary skill in the art to provide the reinforcing members with a

material having high radiopacity doing so would have provided a means to locate the reinforcing members relative to other structures while in use as disclosed by Hopkins and the use of radiopaque bands.

With respect to claim 10, note rejection of claim 7 above.

With respect to claims 11-13, note rejection of claim 5 above.

With respect to claim 20, Hopkins discloses an expandable housing portion (594) that includes a low expansion section with at least one expansion member (590) disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position. ("low expansion section" is being considered by the examiner as a relative phrase which the specification does not clearly define as to what constitutes a "low expansion section"). Also based on the teachings of Amplatz and the pitch and pick of the braid being adjusted as desired for a particular application it would have been obvious to one of ordinary skill in the art to have low expansion sections.

With respect to claim 21, note rejection of claim 4 above.

With respect to claim 22, note rejection of claim 9 above.

With respect to claims 23 and 24, note rejection of claim 7 above.

With respect to claim 25, note rejection of claim 4 above.

With respect to claim 26, Amplatz teaches reinforcing members (Col. 3, lines 39-57) which are fully capable of preventing the low expansion sections from tearing as the expandable housing portion expands from the contracted position to the expanded

position because the reinforcing members provide strength which allowing for expansion.

With respect to claim 41, note rejection of claim 1 above.

With respect to claim 42, note rejection of claim 4 above.

With respect to claims 43, 49, and 50, note rejection of claim 5 above.

With respect to claim 44, note rejection of claim 6 above.

With respect to claims 45, 46, and 48, note rejection of claim 7 above.

With respect to claim 47, note rejection of claim 9 above.

With respect to claim 51, the reinforcing members of Amplatz are fully capable of helping to bias the expandable housing portion in the contracted position based on the pitch and pick used.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Teena Mitchell*  
Teena Mitchell  
Primary Examiner  
Art Unit 3743  
September 24, 2005

TKM  
TKM

<b>Notice of References Cited</b>		Application/Control No.	Applicant(s)/Patent Under Reexamination BOYLE ET AL.	
		Examiner Teena Mitchell	Art Unit 3743	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
A	US-6,517,765	02-2003	Kelley, Gregory	264/510
B	US-5,879,342	03-1999	Kelley, Gregory S.	600/524
C	US-6,887,258	05-2005	Denison et al.	606/200
D	US-6,616,651	09-2003	Stevens, Robert C.	604/524
E	US-5,882,347	03-1999	Mouris-Laan et al.	604/524
F	US-			
G	US-			
H	US-			
I	US-			
J	US-			
K	US-			
L	US-			
M	US-			

**FOREIGN PATENT DOCUMENTS**

*	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
N					
O					
P					
Q					
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S					
T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MAIL STOP AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 29, 2005.

  
\_\_\_\_\_  
Thomas H. Majcher, Reg. No. 31,119

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 09/897,295  
Applicant : William J. Boyle et al.  
Filed : June 29, 2001  
Title : DELIVERY AND RECOVERY SHEATHS  
FOR MEDICAL DEVICES  
Art Unit : 3743  
Examiner : Ragonese, Andrea M.  
  
Docket No.: : ACSES 56001 (2636P) Los Angeles, California  
Customer No. : 24201 November 29, 2005

MAIL STOP AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

AMENDMENT AFTER FINAL OFFICE ACTION

Dear Sir:

This Amendment is responsive to the final Office Action of September 29, 2005, a response to which is due December 29, 2005.

Claims start on page 2.

Remarks start on page 8.

AMENDMENTS TO THE CLAIMS:

The below listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1-2. (Cancelled)

3. (Currently Amended) A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath having an expandable housing portion adapted to receive and maintain the self-expanding medical device in a collapsed condition on the delivery device, the expandable housing portion being adapted to expand between a contracted position and an expanded position, the housing portion having sufficient column strength to maintain the self-expanding medical device in its collapsed condition on its delivery device, wherein:

the expandable housing portion is made primarily from an elastic material which is stretchable between the contracted position and expanded position and includes at least one non-woven reinforcing member associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion of the housing portion.

4. (Currently Amended) The restraining device of claim 3, further including:

a plurality of non-woven reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion.

5. (Previously Presented) The restraining device of claim 4, wherein:

the reinforcing members extend substantially along the length of the expandable housing portion but do not interfere with the expansion of the elastic material.

6. (Previously Presented) The restraining device of claim 5, wherein:

the reinforcing members are elongated bar-like members made from a material having high stiffness.

7. (Original) The restraining device of claim 3, wherein:  
the elastic material is selected from a group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAK.
8. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.
9. (Previously Presented) The restraining device of claim 8, wherein:  
the reinforcing members are loaded with a material having high radiopacity.
10. (Previously Presented) The restraining device of claim 3, wherein:  
the expandable housing portion is made from a substantially tubular-shaped material which is highly elastic and includes a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion.
11. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing members are disposed within the elastic material forming the expandable housing portion.
12. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing members are attached to the surface of the expandable housing portion.
13. (Previously Presented) The restraining device of claim 4, wherein:  
each reinforcing member is disposed along the expandable housing portion to provide additional column strength to the housing portion but does not interfere with the expansion of the housing portion.
14. (Withdrawn) The restraining device of claim 2, further including:  
coil spring associated with the expandable housing portion which provides column strength to the housing portion and is expandable from the contracted position to the expanded position with the elastic material which forms the housing portion.

15. (Withdrawn) The restraining device of claim 14, wherein:  
the coils of the coil spring extend longitudinally along the length of the expandable housing portion.
16. (Withdrawn) The restraining device of claim 14, wherein:  
the coil spring is made from a material selected from a group including nickel-titanium, spring steel and highly flexible plastic.
17. (Withdrawn) The restraining device of claim 2, further including:  
a ring member disposed near the distal tip of the expandable housing portion.
18. (Withdrawn) The restraining device of claim 17, wherein:  
the ring member has a plurality of undulations and is expandable with the elastic material which forms the housing portion.
19. (Withdrawn) The restraining device of claim 18, wherein:  
the ring member is made from a material selected from a group including nickel-titanium, spring steel and highly flexible plastic.
20. (Previously Presented) The restraining device of claim 3, wherein:  
the expandable housing portion includes a low expansion section with at least one expansion member disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position.
21. (Previously Presented) The restraining device of claim 3, wherein:  
the expandable housing portion includes a plurality of low expansion sections and a plurality of expansion members disposed between low expansion sections.
22. (Original) The restraining device of claim 21, wherein:  
the low expansion sections are made from a material loaded with a material having high radiopacity.

23. (Original) The restraining device of claim 21, wherein:  
the expansion members are made from an elastic material selected from a group which includes polyurethane, silicone, polyisoprene and lower durometer PEBAX.
24. (Original) The restraining device of claim 23, wherein:  
the low expansion sections are made from a material selected from a group including cross-linked HDPE, polyolefin and polyamide.
25. (Original) The restraining device of claim 21, wherein:  
the expansion members extend longitudinally along the length of the expandable housing portion.
26. (Original) The restraining device of claim 25, wherein:  
the expansion members include means for preventing the low expansion sections from tearing as the expandable housing portion expands from the contracted position to the expanded position.
27. (Withdrawn) The restraining device of claim 2, wherein:  
the expandable housing portion includes a distal tip section made from highly elastic material which is expandable and contractible between a contracted position and expanded position.
28. (Withdrawn) The restraining device of claim 27, wherein:  
the distal tip section is made from a more elastic material than the remaining portion of the expandable housing portion.
29. (Withdrawn) The restraining device of claim 28, further including:  
an expandable ring member associated with the distal tip section which is expandable between the contracted position and expanded position and is normally biased to the contracted position.

30. (Withdrawn) The restraining device of claim 29, wherein:  
the ring member is encapsulated within the material forming the distal tip section.

31. (Withdrawn) The restraining device of claim 29, wherein:  
the ring member is attached to the outer surface of the distal tip section.

32. (Withdrawn) The restraining device of claim 29, wherein:  
the ring member is made from materials selected from a group including nickel-titanium, stainless steel and highly elastic plastic.

33-40. (Canceled)

41. (Currently Amended) A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath having an expandable housing portion adapted to expand between a contracted position and an expanded position and to maintain the self-expanding medical device in a collapsed condition on the delivery device, and a non-woven reinforcing member associated with the expandable housing portion to cooperatively provide sufficient strength to the expandable housing portion to maintain the self-expanding medical device in its collapsed condition on its delivery device without the reinforcing member interfering with the ability of the expandable housing portion to move between the contracted and expanded positions.

42. (Currently Amended) The restraining device of claim 41, further including:

a plurality of non-woven reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion but which do not interfere with the ability of the expandable housing to move between the contracted and expanded positions.

43. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is embedded in the wall which forms the expandable housing portion.

44. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is an elongated bar-like member made from a material having a stiffness higher than the stiffness of the material used to form the expandable housing portion.
45. (Previously Presented) The restraining device of claim 41, wherein:  
the expandable housing portion is made from an elastic material selected from a group of materials which includes silicone, polyurethane, polyisoprene, and low durometer PEBAX.
46. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.
47. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is loaded with a material having high radiopacity.
48. (Previously Presented) The restraining device of claim 41, wherein:  
the expandable housing portion is made from a substantially tubular-shaped material which is highly elastic and includes a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion.
49. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is molded within the material used to form the expandable housing portion.
50. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is attached to the surface of the expandable housing portion.
51. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member helps to bias the expandable housing portion in the contracted position.

REMARKS

This Amendment is in response to the final Office Action dated September 29, 2005. Claims 3-32 and 41-51 are pending in this application. Claims 14-19 and 27-40 have been withdrawn from consideration in view of an earlier election of species requirement, and claims 1, 2 and 33 - 40 were previously canceled without prejudice. By this Amendment, Applicants have amended claims 3, 4, 41 and 42 to better define the presently claimed invention. Favorable reconsideration of all of the pending claims is respectfully requested.

The Examiner has rejected claims 3-13, 20-26, 41, 42 and 41-44 under 35 U. S. C. 112, first paragraph as failing to comply with the written description requirement. However, Applicants submit that the specification fully supports the claim language "the expansion of the housing portion..." Original claims 1-5 provide the specific support to comply with the written description requirement. Claim 2 states that the expandable housing portion is capable of expanding between an expanded position and a contracted position. This claim does not limit expansion only to radial expansion. Claim 3 recites that the housing portion could be primarily made from an elastic material. Claim 5 states that the reinforcing members do not interfere with the expansion of the elastic material. Therefore, Applicants submit that there is sufficient support for the claim language in question. Applicants respectfully request the Examiner to withdraw the 112 first paragraph rejection of the above-identified claims.

The Examiner has rejected claims 3-13 and 20-26 and 41-51 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,544,279 to Hopkins et al. (the "Hopkins patent") in view of U.S. Patent No. 6,123,715 to Amplatz (the "Amplatz patent") and U. S Patent No. 6,517,765 to Kelley (the "Kelley patent"). Applicants, however, strongly disagree with the Examiner's position that the Amplatz patent and Kelley patent teach the use of reinforcing members for controlling the expandability of a tubing. Initially, it appears that the Examiner may have confused the term "flexibility" with the term "expandability." Flexibility does not mean the ability to expand as stated by the Examiner in paragraph 2 of page 2 of the Office Action. A length of tubing can be flexible but is not necessarily expandable. Applicants submit that the woven reinforcing braids and fabric disclosed in the Amplatz patent and Kelley patent can provide some

flexibility to a length of tubing while still reinforcing the wall of the tubing to prevent the expansion of the tubing. As taught by these patents, the pitch and/or braid pick counts of the woven fabric and braid can be selected to affect the flexibility of the tubing into which they are formed. Therefore, lateral flexibility can be changed. However, these woven braids or fabric are still designed specifically to prevent the expansion of the tubing since this is the main function of the woven braid or fabric. Therefore, while one can increase or decrease the lateral flexibility of the tubing by varying the pitch or braid count, the woven braid or fabric still prevents the tubing from expanding.

Applicants presently claimed invention uses reinforcing members which do not interfere with the expandability of the housing. This feature is simply not shown in any of the cited references. However, for the purposes of gaining allowance of the claims at issue, Applicants have amended the pending claims to recite the use of a non-woven reinforcing member to define the presently claimed invention. Accordingly, Applicants submit that the combination of the Hopkins patent with the Amplatz patent and Kelley patent simply fails to create the structure recited in the present claims. Applicants respectfully request the Examiner to withdraw the § 103 rejection which has been applied to all of the pending claims.

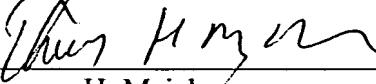
In view of the allowance of generic claims, Applicants respectfully request the Examiner to reconsider claims 14-19 and 27-32 which were previously withdrawn in response to an earlier election of species requirement.

In view of the foregoing, it is respectfully urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above amendments and remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By:   
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,295	06/29/2001	William J. Boyle	ACS-56001 (26361)	1994
24201	7590	12/21/2005	EXAMINER	
FULWIDER PATTON 6060 CENTER DRIVE 10TH FLOOR LOS ANGELES, CA 90045			MICHELL, TEENA KAY	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 12/21/2005

*Advisory Action*

Please find below and/or attached an Office communication concerning this application or proceeding.

FINAL REJECTION

2-MONTH RESPONSE DUE:

3-MONTH RESPONSE DUE: December 29, 2006

NOTICE OF APPEAL DUE:

(6-MONTH PERIOD ENDS) March 29, 2006

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/897,295

Applicant(s)

BOYLE ET AL.

Examiner

Teena Mitchell

Art Unit

3743

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 December 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1.  The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a)  The period for reply expires 3 months from the mailing date of the final rejection.

b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2.  The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3.  The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

- (a)  They raise new issues that would require further consideration and/or search (see NOTE below);
- (b)  They raise the issue of new matter (see NOTE below);
- (c)  They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d)  They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4.  The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5.  Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.

6.  Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7.  For purposes of appeal, the proposed amendment(s): a)  will not be entered, or b)  will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 3-13, 20-26 and 41-51.

Claim(s) withdrawn from consideration: 14-19 and 27-32.

**AFFIDAVIT OR OTHER EVIDENCE**

8.  The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9.  The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

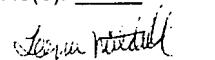
10.  The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11.  The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

12.  Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_

13.  Other: \_\_\_\_\_

  
Teena Mitchell  
Primary Examiner  
Art Unit: 3743

Continuation of 3. NOTE: The addition of the limitation of "non-woven" not previously presented, in the claims would require new search and consideration.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REQUEST  
FOR  
CONTINUED EXAMINATION (RCE)  
TRANSMITTAL

Address to:  
Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Application Number	09/897,295
Filing Date	June 29, 2001
First Named Inventor	William J. Boyle et al.
Art Unit	3743
Examiner Name	Teena K. Mitchell
Attorney Docket Number	ACSES-56001 (2636P)

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.

Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED**

Signature		Date	December 29, 2005
Name (Print / Type)	Thomas H. Majcker for FULWIDER PATTON	Registration No.	31,119

**CERTIFICATE OF MAILING OR TRANSMISSION**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 or facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

Signature		Date	December 29, 2005
Name (Print / Type)	Thomas H. Majchep		

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing the burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



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FULWIDER PATTON LLP

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,295	06/29/2001	William J. Boyle	ACS-56001 (26361)	1994
24201	7590	03/20/2006	ACSES	EXAMINER
FULWIDER PATTON 6060 CENTER DRIVE 10TH FLOOR LOS ANGELES, CA 90045			MITCHELL, TEENA KAY	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 03/20/2006

*Response Due June 20, 2006*

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/897,295	BOYLE ET AL.
	Examiner Teena Mitchell	Art Unit 3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 January 2006.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 3-32 and 41-51 is/are pending in the application.
- 4a) Of the above claim(s) 14-19 and 27-32 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 3-13,20-26 and 41-51 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/3/06 has been entered.

### ***Claim Rejections - 35 USC § 112***

**The following is a quotation of the first paragraph of 35 U.S.C. 112:**

**The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

**Claims 3-13, 20-26, 41-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation of "...non-woven reinforcing member..." which was not previously presented in the originally filed specification constitutes new matter.**

### ***Claim Rejections - 35 USC § 103***

**The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

**(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.**

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.**

**Claims 3-13, 20-26, and 41-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hopkins et.al. (6,544,279) in view of Amplatz (6,123,715) and Kelley (6,517,765).**

Hopkins in a restraining device discloses a restraining sheath having an expandable housing portion (594) adapted to receive and maintain the self-expanding medical device (588) in a collapsed condition on the delivery device, the expandable housing portion being adapted to expand between a contracted position (Fig. 23A) and an expanded position (Fig. 23B), the housing portion having sufficient column strength to maintain the self-expanding medical device (588) in its collapsed condition on its delivery device, wherein the expandable housing portion (594) is made primarily from an elastic material which is stretchable between the contracted position and expanded position. With respect to the limitation of the reinforcing member being non-woven, Hopkins does not teach a non-woven. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the reinforcing member be a non-woven, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design consideration. Applicant has not disclosed that having the reinforcing member

being a non-woven provides an advantage, is used for a particular purpose, or solves any stated problem. One of ordinary skill in the art furthermore would have expected Applicant's invention to perform equally well with other materials, which provide elastic properties because the housing portion would still be able to expand. Therefore, it would have been an obvious matter of design consideration to modify Hopkins/Amplatz to obtain the invention as specified in claim 3 with the reinforcing member being a non-woven

The difference between Hopkins and claim 3 is a reinforcing member associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion of the housing portion.

Amplatz in an intravascular occlusion device teaches the use of tubular braids in medical devices providing reinforcing means to the wall of a guiding catheter, which may be adjusted as desired for a particular application by the pitch and pick of the fabric (Col. 3, lines 39-57; Col. 4, lines 11-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the expandable housing portion of Hopkins to employ any well-known tubular braids doing so would have provided a means to reinforce the expandable housing portion. Further the teachings of Kelley teach the use of braids in varying braid pick counts vary the flexibility of the tubing (Col. 1, lines 40-67 and Col. 2, lines 1-15). Based on a standard dictionary definition of "flexible, Capable of being bent or flexed; capable of withstanding stress without structural injury: Pliable. "pliable" meaning, easily bent or shaped: Malleable, capable of being shaped or formed. Therefore, based on the teachings of braids of

Kelley; the tubular braids of Amplatz could be adjusted to allow for expansion of the housing portion and therefore, would not interfere with the expansion of the housing portion, as one of ordinary skill in the art would know.

With respect to claim 4, Amplatz does not teach a plurality of reinforcing members. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have a plurality of reinforcing members, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). With respect to the non-woven note rejection of claim 3 above.

With respect to claim 5, Amplatz does not teach the reinforcing member extending substantially along the length of the expandable housing portion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the reinforcing member extending substantially along the length of the expandable housing portion, since it has been held that rearranging parts of an invention involves only routine skill in the art and applicant has not disclosed that having the reinforcing members extending substantially along the length of the expandable housing portion provides an advantage or solves a particular problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the reinforcing member positioned in any other arrangement of the housing portion because the housing portion would still be expandable. Therefore, it would have been an obvious matter of design consideration to modify Hopkin/Amplatz to obtain the invention as specified in claim 5.

With respect to claim 6, Amplatz teaches the reinforcing members are elongated bar-like members made from a material having a high stiffness (Col. 4, lines 11-65).

With respect to claim 7, Hopkins does not specifically disclose the elastic material selected from the group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAK. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the elastic material selected from the group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAK, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design consideration. Applicant has not disclosed that having the elastic member selected from the group of materials, which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAK provides an advantage, is used for a particular purpose, or solves any stated problem. One of ordinary skill in the art furthermore would have expected Applicant's invention to perform equally well with other materials, which provide elastic properties because the housing portion would still be able to expand. Therefore, it would have been an obvious matter of design consideration to modify Hopkins/Amplatz to obtain the invention as specified in claim 7.

With respect to claim 8, note rejection of claim 7 above.

With respect to claim 9, Hopkins/Amplatz do not disclose/teach the reinforcing members loaded with a material having high radiopacity. However, Hopkins does disclose the use of radiopaque bands (596, 598) providing a means so that positions of

the bands relative to one another may be accurately determined. It would have been obvious to one of ordinary skill in the art to provide the reinforcing members with a material having high radiopacity doing so would have provided a means to locate the reinforcing members relative to other structures while in use as disclosed by Hopkins and the use of radiopaque bands.

With respect to claim 10, note rejection of claim 7 above.

With respect to claims 11-13, note rejection of claim 5 above.

With respect to claim 20, Hopkins discloses an expandable housing portion (594) that includes a low expansion section with at least one expansion member (590) disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position. ("low expansion section" is being considered by the examiner as a relative phrase, which the specification does not clearly define as to what constitutes a "low expansion section"). Also based on the teachings of Amplatz and the pitch and pick of the braid being adjusted as desired for a particular application it would have been obvious to one of ordinary skill in the art to have low expansion sections.

With respect to claim 21, note rejection of claim 4 above.

With respect to claim 22, note rejection of claim 9 above.

With respect to claims 23 and 24, note rejection of claim 7 above.

With respect to claim 25, note rejection of claim 4 above.

With respect to claim 26, Amplatz teaches reinforcing members (Col. 3, lines 39-57) which are fully capable of preventing the low expansion sections from tearing as the

expandable housing portion expands from the contracted position to the expanded position because the reinforcing members provide strength which allowing for expansion.

With respect to claim 41, note rejection of claim-3 above.

With respect to claim 42, note rejection of claim 4 above.

With respect to claims 43, 49, and 50, note rejection of claim 5 above.

With respect to claim 44, note rejection of claim 6 above.

With respect to claims 45, 46, and 48, note rejection of claim 7 above.

With respect to claim 47, note rejection of claim 9 above.

With respect to claim 51, the reinforcing members of Amplatz are fully capable of helping to bias the expandable housing portion in the contracted position based on the pitch and pick used (Col. 4, lines 10-65).

***Claim Rejections - 35 USC § 102***

**The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless –**

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

**Claims 3-6, 20, 21, 25, 41, 42, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Querns et.al. (5,944,691).**

Querns discloses a restraining sheath (10) having an expandable housing portion (32, 34) adapted to receive and maintain the self-expanding medical device in a

collapsed condition on the delivery device, the expandable housing portion being adapted to expand between a contracted position and an expanded position (Figs. 2, 3), the housing portion having sufficient column strength to maintain the self-expanding medical device in its collapsed condition on its delivery device, wherein: the expandable housing portion is made primarily from an elastic material which is stretchable between the contracted position and expanded position and includes at least one non-woven reinforcing member (52) associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion of the housing portion (Figs. 2, 3).

With respect to claim 4, Querns discloses a plurality of non-woven reinforcing members (52) associated with the expandable housing portion to provide additional column strength to the housing portion.

With respect to claim 5, Querns discloses wherein the reinforcing members (52) extend substantially along the length of the expandable housing portion but do not interfere with the expansion of the elastic material (Figs. 2, 3).

With respect to claim 6, Querns discloses the reinforcing members (52) are elongated bar-like members made from a material having high stiffness.

With respect to claim 20, Querns discloses the expandable housing portion includes a low expansion section with at least one expansion member disposed within the low expansion section (54) to provide the elasticity needed to move the housing portion between the contracted position and expanded position (Figs. 2, 3).

With respect to claim 21, Querns discloses a plurality of low expansion sections (52) and a plurality of expansion members (54) disposed between low expansion sections (52).

With respect to claim 25, Querns discloses the expansion members (54) extend longitudinally along the length of the expandable housing portion.

With respect to claim 41, Querns discloses a restraining sheath (10) having an expandable housing portion (32, 34) adapted to expand between a contracted position and an expanded position and to maintain the self-expanding medial device in a collapsed condition on the delivery device, and a non-woven reinforcing member (52) associated with the expandable housing portion to maintain to cooperatively provide sufficient strength to the expandable housing portion to maintain the self-expanding medical device in its collapsed condition on its delivery device without the reinforcing member interfering with the ability of the expandable housing portion to move between the contracted and expanded positions (Figs. 2, 3).

With respect to claim 42, Querns discloses a plurality of non-woven reinforcing members (52) associated with the expandable housing portion to provide additional column strength to the housing portion but which do not interfere with the ability of the expandable housing to move between the contracted and expanded positions (Figs. 2, 3).

With respect to claim 44, Querns discloses the reinforcing member (52) is an elongated bar-like member (52) made from a material having a stiffness higher than the stiffness of the material used to form the expandable housing portion.

With respect to claim 51, Querns discloses wherein the reinforcing member (52) helps to bias the expandable housing portion in the contracted position.

***Claim Rejections - 35 USC § 103***

**The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

**(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.**

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.**

**Claims 7, 8, and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Querns (5,944,691).**

With respect to claim 7, Querns does not specifically disclose the elastic material selected from the group of materials, which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAK. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the elastic material selected from the group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAK, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability

for the intended use as a matter of design consideration. Applicant has not disclosed that having the elastic member selected from the group of materials, which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAK provides an advantage, is used for a particular purpose, or solves any stated problem. One of ordinary skill in the art furthermore would have expected Applicant's invention to perform equally well with other materials, which provide elastic properties because the housing portion would still be able to expand. Therefore, it would have been an obvious matter of design consideration to modify Querns to obtain the invention as specified in claim 7.

With respect to claim 8, note rejection of claim 7 above.

With respect to claim 10-13, note rejection of claim 7 above.

With respect to claim 22, note rejection of claim 9 above.

With respect to claims 23 and 24, note rejection of claim 7 above.

With respect to claims 43, 49, and 50, note rejection of claim 5 above.

With respect to claims 45, 46, and 48, note rejection of claim 7 above.

With respect to claim 47, note rejection of claim 9 above.

**Claims 9, 22, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Querns (5,944,691) in view of Hopkins (6,544,279).**

The difference between Querns and claim 9 is the reinforcing members loaded with a material having high radiopacity. However, Hopkins does disclose the use of radiopaque bands (596, 598) providing a means so that positions of the bands relative to one another may be accurately determined. It would have been obvious to one of

ordinary skill in the art at the time the invention was made to modify the reinforcing members of Querns with a material having a high radiopacity doing so would have provided a means to locate the reinforcing members relative to other structures while in use as disclosed by Hopkins and the use of radiopaque bands.

With respect to claims 22 and 47, note rejection of claim 9 above.

***Response to Arguments***

Applicant's arguments filed 1/03/06 have been fully considered but they are not persuasive. Applicant argues that the Hopkins/Amplatz is not expandable, however, applicant is referred to the comments in the rejection above with respect to expandable (note claim 3 above; also note Col. 4, lines 10-65 which teach shape memory alloy such as NiTi which are very elastic-they are said to be "superelastic" or "pseudoelastic"). Applicant also adds the limitation of "non-woven" to the claims, while applicant list materials in the specification for the reinforcing member, which may be non-woven, there is nothing in the specification which states the reinforcing members are non-woven, therefore this limitation to the claims is considered new matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Teena Mitchell*  
Teena Mitchell  
Primary Examiner  
Art Unit 3743  
March 14, 2006

*TKM*  
TKM

## Notice of References Cited

Application/Control No.

09/897,295

Applicant(s)/Patent Under

Reexamination  
BOYLE ET AL.

Examiner

Teena Mitchell

Art Unit

3743

Page 1 of 1

### U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2002/0183781	12-2002	Casey et al.	606/198
*	B	US-5,944,691	08-1999	Querns et al.	604/104
*	C	US-5,176,659	01-1993	Mancini, Mario	604/523
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

### FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

### NON-PATENT DOCUMENTS

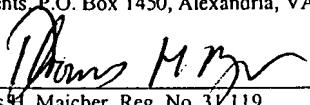
*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)

Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 16, 2006.

  
\_\_\_\_\_  
Thomas H. Majcher, Reg. No. 31,119

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 09/897,295

Applicant : William J. Boyle et al.

Filed : June 29, 2001

Title : DELIVERY AND RECOVERY SHEATHS  
FOR MEDICAL DEVICES

Art Unit : 3743

Examiner : Ragonese, Andrea M.

Docket No.: : ACSES 56001 (2636P)

Los Angeles, California

Customer No. : 24201

June 16, 2006

MAIL STOP AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

AMENDMENT

Dear Sir:

This Amendment is responsive to the Office Action of March 20, 2006, a response to which is due June 20, 2006.

Claims start on page 2.

Remarks start on page 8.

AMENDMENTS TO THE CLAIMS:

The below listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1-2. (Cancelled)

3. (Currently Amended) A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath having an expandable housing portion adapted to receive and maintain the self-expanding medical device in a collapsed condition on the delivery device, the expandable housing portion being adapted to expand move between a contracted position and expanded position, the housing portion having sufficient column strength to maintain the self-expanding medical device in its collapsed condition on its delivery device, wherein:

the expandable housing portion is made primarily from an elastic material which is stretchable movable between the contracted position and expanded position and includes at least one non-woven reinforcing member associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion.

4. (Previously Presented) The restraining device of claim 3, further including:

a plurality of non-woven reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion.

5. (Previously Presented) The restraining device of claim 4, wherein:

the reinforcing members extend substantially along the length of the expandable housing portion but do not interfere with the expansion of the elastic material.

6. (Previously Presented) The restraining device of claim 5, wherein:

the reinforcing members are elongated bar-like members made from a material having high stiffness.

7. (Original) The restraining device of claim 3, wherein:  
the elastic material is selected from a group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAK.
8. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.
9. (Previously Presented) The restraining device of claim 8, wherein:  
the reinforcing members are loaded with a material having high radiopacity.
10. (Previously Presented) The restraining device of claim 3, wherein:  
the expandable housing portion is made from a substantially tubular-shaped material which is highly elastic and includes a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion.
11. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing members are disposed within the elastic material forming the expandable housing portion.
12. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing members are attached to the surface of the expandable housing portion.
13. (Previously Presented) The restraining device of claim 4, wherein:  
each reinforcing member is disposed along the expandable housing portion to provide additional column strength to the housing portion but does not interfere with the expansion of the housing portion.
14. (Withdrawn) The restraining device of claim 2, further including:  
coil spring associated with the expandable housing portion which provides column strength to the housing portion and is expandable from the contracted position to the expanded position with the elastic material which forms the housing portion.

15. (Withdrawn) The restraining device of claim 14, wherein:  
the coils of the coil spring extend longitudinally along the length of the expandable housing portion.
16. (Withdrawn) The restraining device of claim 14, wherein:  
the coil spring is made from a material selected from a group including nickel-titanium, spring steel and highly flexible plastic.
17. (Withdrawn) The restraining device of claim 2, further including:  
a ring member disposed near the distal tip of the expandable housing portion.
18. (Withdrawn) The restraining device of claim 17, wherein:  
the ring member has a plurality of undulations and is expandable with the elastic material which forms the housing portion.
19. (Withdrawn) The restraining device of claim 18, wherein:  
the ring member is made from a material selected from a group including nickel-titanium, spring steel and highly flexible plastic.
20. (Previously Presented) The restraining device of claim 3, wherein:  
the expandable housing portion includes a low expansion section with at least one expansion member disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position.
21. (Previously Presented) The restraining device of claim 3, wherein:  
the expandable housing portion includes a plurality of low expansion sections and a plurality of expansion members disposed between low expansion sections.
22. (Original) The restraining device of claim 21, wherein:  
the low expansion sections are made from a material loaded with a material having high radiopacity.

23. (Original) The restraining device of claim 21, wherein:  
the expansion members are made from an elastic material selected from a group which includes polyurethane, silicone, polyisoprene and lower durometer PEBAK.
24. (Original) The restraining device of claim 23, wherein:  
the low expansion sections are made from a material selected from a group including cross-linked HDPE, polyolefin and polyamide.
25. (Original) The restraining device of claim 21, wherein:  
the expansion members extend longitudinally along the length of the expandable housing portion.
26. (Original) The restraining device of claim 25, wherein:  
the expansion members include means for preventing the low expansion sections from tearing as the expandable housing portion expands from the contracted position to the expanded position.
27. (Withdrawn) The restraining device of claim 2, wherein:  
the expandable housing portion includes a distal tip section made from highly elastic material which is expandable and contractible between a contracted position and expanded position.
28. (Withdrawn) The restraining device of claim 27, wherein:  
the distal tip section is made from a more elastic material than the remaining portion of the expandable housing portion.
29. (Withdrawn) The restraining device of claim 28, further including:  
an expandable ring member associated with the distal tip section which is expandable between the contracted position and expanded position and is normally biased to the contracted position.

30. (Withdrawn) The restraining device of claim 29, wherein:  
the ring member is encapsulated within the material forming the distal tip section.
31. (Withdrawn) The restraining device of claim 29, wherein:  
the ring member is attached to the outer surface of the distal tip section.
32. (Withdrawn) The restraining device of claim 29, wherein:  
the ring member is made from materials selected from a group including nickel-titanium, stainless steel and highly elastic plastic.

33-40. (Canceled)

41. (Currently Amended) A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:  
a restraining sheath having an expandable housing portion adapted to ~~expand move~~ between a contracted position and an expanded position and to maintain the self-expanding medical device in a collapsed condition on the delivery device, and a non-woven reinforcing member associated with the expandable housing portion to cooperatively provide sufficient strength to the expandable housing portion to maintain the self-expanding medical device in its collapsed condition on its delivery device without the reinforcing member interfering with the ability of the expandable housing portion to move between the contracted and expanded positions.
42. (Previously Presented) The restraining device of claim 41, further including:  
a plurality of non-woven reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion but which do not interfere with the ability of the expandable housing to move between the contracted and expanded positions.
43. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is embedded in the wall which forms the expandable housing portion.

44. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is an elongated bar-like member made from a material having a stiffness higher than the stiffness of the material used to form the expandable housing portion.
45. (Previously Presented) The restraining device of claim 41, wherein:  
the expandable housing portion is made from an elastic material selected from a group of materials which includes silicone, polyurethane, polyisoprene, and low durometer PEBAK.
46. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.
47. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is loaded with a material having high radiopacity.
48. (Previously Presented) The restraining device of claim 41, wherein:  
the expandable housing portion is made from a substantially tubular-shaped material which is highly elastic and includes a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion.
49. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is molded within the material used to form the expandable housing portion.
50. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is attached to the surface of the expandable housing portion.
51. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member helps to bias the expandable housing portion in the contracted position.

REMARKS

This Amendment is in response to the Office Action dated March 20, 2006. Claims 3-32 and 41-51 are pending in this application. Claims 14-19 and 27-32 have been withdrawn from consideration in view of an earlier election of species requirement, and claims 1, 2 and 33 - 40 were previously canceled without prejudice. By this Amendment, claims 3 and 41 have been amended to clarify the presently claimed invention. These amendments were not made for the purpose of distinguishing the presently claimed invention over the art of record. Favorable reconsideration of all of the pending claims is respectfully requested in view of the remarks below.

The Examiner has rejected claims 3-13, 20-26, 41-51 under 35 U. S. C. 112, first paragraph as failing to comply with the written description requirement. The Examiner believes that the term "non-woven reinforcing member" recited in the present claims constitutes new matter. Applicants note, however, that the Examiner has acknowledged that the specification lists materials for the reinforcing member which are non-woven materials. Reference is made to page 13, lines 12-15 of the Office Action. Apparently, the Examiner is taking the position that the term "non-woven" somehow constitutes new matter since this actual term does not appear in the specification. However, Applicant is entitled to use appropriate terminology in the claims to define the presently claimed invention provided that there is adequate support for those terms in the specification. The Examiner has acknowledged that there is sufficient support in the specification to support this claim language. Therefore, Applicants submit that there is no basis for the Examiner's position that this claim language constitutes new matter. Applicants respectfully request the Examiner to withdraw the Section 112, first paragraph rejection of the above-identified claims.

The Examiner has rejected claims 3-6, 20, 21, 25, 41, 42 and 44 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,944,691 to Querns et al. (the "Querns patent"). Applicants strongly disagree with the Examiner's characterization of the Querns patent. The Querns patent is quite clear that the catheter described therein is capable of being irreversibly expanded from a first diameter to a second diameter. As such, once expanded, the Querns catheter remains permanently expanded. Therefore, the Examiner's position that the Querns patent describes a sheath adapted to expand between a contracted position and expanded position

is incorrect. The catheter of the Querns patent only expands once from a smaller diameter to a larger diameter. Therefore, it is incapable of moving between expanded and contracted positions, as recited in the claims. While Applicants believe that claims 3 and 41 were sufficiently clear, Applicants have amended the claim language of claims 3 and 41 to clarify that the expandable housing portion is movable between the contracted and expanded positions, i.e., the expandable housing can expand and collapse between these positions. Clearly, the catheter described in the Querns patent is incapable of expanding and collapsing between these positions. As such, Applicants respectfully request the Examinee to withdraw the Querns patent as an anticipatory reference.

The Examiner has rejected claims 3-13 and 20-26 and 41-51 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,544,279 to Hopkins et al. (the "Hopkins patent") in view of U.S. Patent No. 6,123,715 to Amplatz (the "Amplatz patent") and U.S. Patent No. 6,517,765 to Kelley (the "Kelley patent"). Applicants again strongly disagree with the Examiner's position that the Amplatz patent and Kelley patent teach the use of reinforcing members for controlling the expandability of a tubular member. The Amplatz patent merely makes reference to the fact that tubular braids have been used to reinforce the wall of a guiding catheter. Guiding catheters are generally designed to be flexible and will revert to a pre-formed shape to help position the catheter in the patient's vasculature. In this regard, the guiding catheter will be inserted into the patient's vasculature in a relative linear configuration and will revert to its pre-formed shape after reaching its target location. This requires flexibility along the length of the guiding catheter, but not radial expandability, since the tubular structure of the guiding catheter is not designed to expand radially. For this reason, tubular braids have been used to reinforce the wall of the guiding catheter since the intertwining braid geometry is designed to inhibit expansion, but allow lateral flexibility.

Applicants respectfully submit that the Examiner's position that the Hawkins patent could be combined with the Amplatz patent to achieve the recited structural arrangement is incorrect. First, the Hawkins patent fails to disclose the use of any reinforcing member with its elastic housing, no less a non-woven reinforcing member. The Amplatz patent only discloses that woven braids have been used to reinforce the walls of a guiding catheter. Therefore, one would not think of using a woven braid with an elastic housing since woven braids are designed to inhibit radial expansion. The housing 594 of the Hawkins patent is designed to radially expand

as it contacts the expander 590. The placement of a woven braid on the housing 594 would simply inhibit the housing 594 from expanding.

The Kelley patent merely teaches that the pitch and/or braid pick counts of the woven fabric and braid can be selected to affect the flexibility of the tubing into which they are formed. Therefore, lateral flexibility can be changed. However, these woven braids or fabric are still designed specifically to prevent the expansion of the tubing since this is the main function of the woven braid or fabric. Therefore, while one can increase or decrease the lateral flexibility of the tubing by varying the pitch or braid count, the woven braid or fabric still prevents the tubing from expanding.

Therefore, the combination of the Hawkins patent with the Amplatz patent or Kelley patent simply works against the desired radial expandability of the housing 594. Therefore, one would simply not combine the teachings of the Amplatz patent, or the Kelley patent, with the Hawkins patent. Applicants' presently claimed invention uses reinforcing members which do not interfere with the expandability and contraction of the housing, yet provide increased column (axial) strength to the housing. This feature is simply not shown in any of the cited references. Applicants respectfully request the Examiner to withdraw all of the obviousness rejections based on the combination of the Hawkins patent with the Amplatz patent or Kelley patent.

The Examiner has rejected claims 7, 8 and 10-13 under 35 U.S.C. § 103(a) as being unpatentable over the Querns patent. Claims 9, 22 and 47 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Querns patent in view of the Hawkins patent. As addressed above, the Querns patent fails to disclose the basic structure of the presently claimed invention. In fact, the Querns patent teaches away from the presently defined invention since the Querns catheter is irreversibly expanded from one diameter to a larger diameter. Accordingly, the claims at issue would not have been obvious in view of the Querns patent by itself or in combination with the Hawkins patent. Accordingly, Applicants respectfully request the Examiner to withdraw the obviousness rejections of these claims as well.

In view of the allowance of generic claims, Applicants respectfully request the Examiner to reconsider claims 14-19 and 27-32 which were previously withdrawn in response to an earlier election of species requirement.

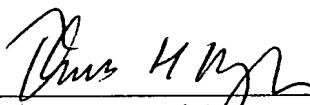
In view of the foregoing, it is respectfully urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above amendments and remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

FULWIDER PATTON LLP

By:

  
Thomas H. Majcher  
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THM/lm

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,295	06/29/2001	William J. Boyle	ACS-56001 (26361)	1994
24201	7590	09/11/2006	EXAMINER	
FULWIDER PATTON 6060 CENTER DRIVE 10TH FLOOR LOS ANGELES, CA 90045			MITCHELL, TEENA KAY	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/897,295	BOYLE ET AL	
	Examiner Teena Mitchell	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 June 2006.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 3-32 and 41-51 is/are pending in the application.
  - 4a) Of the above claim(s) 14-19 and 27-32 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 3-13,20-26,41-51 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

**The following is a quotation of the first paragraph of 35 U.S.C. 112:**

**The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

**Claims 3-13, 20-26, 41-51 are rejected under 35 U.S.C. 112, first paragraph,**

**as failing to comply with the written description requirement. The claim(s)**

**contains subject matter, which was not described in the specification in such a way as**

**to reasonably convey to one skilled in the relevant art that the inventor(s), at the time**

**the application was filed, had possession of the claimed invention. The limitation of**

**"...non-woven reinforcing member..." which was not previously presented in the**

**originally filed specification constitutes new matter.**

### *Claim Rejections - 35 USC § 103*

**The following is a quotation of 35 U.S.C. 103(a) which forms the basis for**

**all obviousness rejections set forth in this Office action:**

**(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.**

**The text of those sections of Title 35, U.S. Code not included in this action**

**can be found in a prior Office action.**

**Claims 3-13, 20-26, and 41-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hopkins et.al. (6,544,279) in view of Amplatz (6,123,715) and Kelley (6,517,765).**

Hopkins in a restraining device discloses a restraining sheath having an expandable housing portion (594) adapted to receive and maintain the self-expanding medical device (588) in a collapsed condition on the delivery device, the expandable housing portion being adapted to move between a contracted position (Fig. 23A) and an expanded position (Fig. 23B), the housing portion having sufficient column strength to maintain the self-expanding medical device (588) in its collapsed condition on its delivery device, wherein the expandable housing portion (594) is made primarily from an elastic material which is movable between the contracted position and expanded position. With respect to the limitation of the reinforcing member being non-woven, Hopkins does not teach a non-woven. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the reinforcing member be a non-woven, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design consideration. Applicant has not disclosed that having the reinforcing member being a non-woven provides an advantage, is used for a particular purpose, or solves any stated problem. One of ordinary skill in the art furthermore would have expected Applicant's invention to perform equally well with other materials, which provide elastic properties because the housing portion would still be able to expand. Therefore, it would have been an obvious matter of design consideration to modify Hopkins/Amplatz

to obtain the invention as specified in claim 3 with the reinforcing member being a non-woven

The difference between Hopkins and claim 3 is a reinforcing member associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion.

Amplatz in an intravascular occlusion device teaches the use of tubular braids in medical devices providing reinforcing means to the wall of a guiding catheter, which may be adjusted as desired for a particular application by the pitch and pick of the fabric (Col. 3, lines 39-57; Col. 4, lines 11-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the expandable housing portion of Hopkins to employ any well-known tubular braids doing so would have provided a means to reinforce the expandable housing portion. Further the teachings of Kelley teach the use of braids in varying braid pick counts vary the flexibility of the tubing (Col. 1, lines 40-67 and Col. 2, lines 1-15). Based on a standard dictionary definition of "flexible, Capable of being bent or flexed; capable of withstanding stress without structural injury: Pliable. "pliable" meaning, easily bent or shaped: Malleable, capable of being shaped or formed. Therefore, based on the teachings of braids of Kelley, the tubular braids of Amplatz could be adjusted to allow for expansion of the housing portion and therefore, would not interfere with the expansion of the housing portion, as one of ordinary skill in the art would know.

With respect to claim 4, Amplatz does not teach a plurality of reinforcing members. It would have been obvious to one of ordinary skill in the art at the time the

invention was made to have a plurality of reinforcing members, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). With respect to the non-woven note rejection of claim 3 above.

With respect to claim 5, Amplatz does not teach the reinforcing member extending substantially along the length of the expandable housing portion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the reinforcing member extending substantially along the length of the expandable housing portion, since it has been held that rearranging parts of an invention involves only routine skill in the art and applicant has not disclosed that having the reinforcing members extending substantially along the length of the expandable housing portion provides an advantage or solves a particular problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the reinforcing member positioned in any other arrangement of the housing portion because the housing portion would still be expandable. Therefore, it would have been an obvious matter of design consideration to modify Hopkin/Amplatz to obtain the invention as specified in claim 5.

With respect to claim 6, Amplatz teaches the reinforcing members are elongated bar-like members made from a material having a high stiffness (Col. 4, lines 11-65).

With respect to claim 7, Hopkins does not specifically disclose the elastic material selected from the group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAK. It would have been obvious to one of

ordinary skill in the art at the time the invention was made to have the elastic material selected from the group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAK, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design consideration. Applicant has not disclosed that having the elastic member selected from the group of materials, which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAK provides an advantage, is used for a particular purpose, or solves any stated problem. One of ordinary skill in the art furthermore would have expected Applicant's invention to perform equally well with other materials, which provide elastic properties because the housing portion would still be able to expand. Therefore, it would have been an obvious matter of design consideration to modify Hopkins/Amplatz to obtain the invention as specified in claim 7.

With respect to claim 8, note rejection of claim 7 above.

With respect to claim 9, Hopkins/Amplatz do not disclose/teach the reinforcing members loaded with a material having high radiopacity. However, Hopkins does disclose the use of radiopaque bands (596, 598) providing a means so that positions of the bands relative to one another may be accurately determined. It would have been obvious to one of ordinary skill in the art to provide the reinforcing members with a material having high radiopacity doing so would have provided a means to locate the reinforcing members relative to other structures while in use as disclosed by Hopkins and the use of radiopaque bands.

With respect to claims 43, 49, and 50, note rejection of claim 5 above.

With respect to claim 44, note rejection of claim 6 above.

With respect to claims 45, 46, and 48, note rejection of claim 7 above.

With respect to claim 47, note rejection of claim 9 above.

With respect to claim 51, the reinforcing members of Amplatz are fully capable of helping to bias the expandable housing portion in the contracted position based on the pitch and pick used (Col. 4, lines 10-65).

#### ***Response to Arguments***

Applicant's arguments filed 6/19/06 have been fully considered but they are not persuasive. First with respect to the 112 first paragraph and the new matter of "non-woven" limitations previously presented. The examiner on page 13, of the previous office action stated, "...while applicant list materials in the specification for the reinforcing member, which may be non-woven, there is nothing in the specification which states the reinforcing members are non-woven, therefore this limitation is considered new matter. While a list of material may be non-woven, unless stated that the materials are non-woven, does not mean the materials are non-woven. Therefore the applicant needs to provide some evidence that the list of materials are non-woven. The 112 first paragraph rejection is being maintained by the examiner. As to the arguments that the Hopkins with Amplatz or Kelley patent works against the desired radial expandability of the housing, applicant is directed back to claim 3 above and Col. 4, lines 10-65 which teach NiTi which are very elastic they are said to be super elastic therefore does meet the limitations of the claim of providing column strength to the

With respect to claim 10, note rejection of claim 7 above.

With respect to claims 11-13, note rejection of claim 5 above.

With respect to claim 20, Hopkins discloses an expandable housing portion (594) that includes a low expansion section with at least one expansion member (590) disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position. ("low expansion section" is being considered by the examiner as a relative phrase, which the specification does not clearly define as to what constitutes a "low expansion section").

Also based on the teachings of Amplatz and the pitch and pick of the braid being adjusted as desired for a particular application it would have been obvious to one of ordinary skill in the art to have low expansion sections.

With respect to claim 21, note rejection of claim 4 above.

With respect to claim 22, note rejection of claim 9 above.

With respect to claims 23 and 24, note rejection of claim 7 above.

With respect to claim 25, note rejection of claim 4 above.

With respect to claim 26, Amplatz teaches reinforcing members (Col. 3, lines 39-57) which are fully capable of preventing the low expansion sections from tearing as the expandable housing portion expands from the contracted position to the expanded position because the reinforcing members provide strength which allowing for expansion.

With respect to claim 41, note rejection of claim 3 above.

With respect to claim 42, note rejection of claim 4 above.

housing portion but not interfering with the expansion or contraction of the housing portion.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (571) 272-4798. The examiner can normally be reached on Monday-Friday however the examiner is on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Teena Mitchell*  
Teena Mitchell  
Primary Examiner  
Art Unit 3743  
September 3, 2006

*TKM*  
TKM

**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MAIL STOP AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 8, 2006.

Thomas H. Majcher, Reg. No. 31,119

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appn. No. : 09/897,295  
Applicant : William J. Boyle et al.  
Filed : June 29, 2001  
Title : DELIVERY AND RECOVERY SHEATHS  
FOR MEDICAL DEVICES  
Art Unit : 3743  
Examiner : Mitchell, Teena Kay  
Docket No.: : ACSES 56001 (2636P) Los Angeles, California  
Customer No. : 24201 November 8, 2006

MAIL STOP AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

## AMENDMENT AFTER FINAL

Dear Sir:

This Amendment After Final is responsive to the final Office Action dated September 11, 2006, a response to which is due December 11, 2006. This Amendment is being filed within two (2) months of the issuance of the final Office Action.

Claims start on page 2.

Remarks start on page 8.

AMENDMENTS TO THE CLAIMS:

The below listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1-2. (Cancelled)

3. (Currently Amended) A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath having an expandable housing portion adapted to receive and maintain the self-expanding medical device in a collapsed condition on the delivery device, the expandable housing portion being adapted to move between a contracted position and expanded position, the housing portion having sufficient column strength to maintain the self-expanding medical device in its collapsed condition on its delivery device, wherein:

the expandable housing portion is made primarily from an elastic material which is movable between the contracted position and expanded position and includes at least one [non-woven] reinforcing member associated therewith which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion.

4. (Currently Amended) The restraining device of claim 3, further including:

a plurality of [non-woven] reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion.

5. (Previously Presented) The restraining device of claim 4, wherein:

the reinforcing members extend substantially along the length of the expandable housing portion but do not interfere with the expansion of the elastic material.

6. (Previously Presented) The restraining device of claim 5, wherein:

the reinforcing members are elongated bar-like members made from a material having high stiffness.

7. (Original) The restraining device of claim 3, wherein:  
the elastic material is selected from a group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAK.
8. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.
9. (Previously Presented) The restraining device of claim 8, wherein:  
the reinforcing members are loaded with a material having high radiopacity.
10. (Previously Presented) The restraining device of claim 3, wherein:  
the expandable housing portion is made from a substantially tubular-shaped material which is highly elastic and includes a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion.
11. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing members are disposed within the elastic material forming the expandable housing portion.
12. (Previously Presented) The restraining device of claim 4, wherein:  
the reinforcing members are attached to the surface of the expandable housing portion.
13. (Previously Presented) The restraining device of claim 4, wherein:  
each reinforcing member is disposed along the expandable housing portion to provide additional column strength to the housing portion but does not interfere with the expansion of the housing portion.
14. (Withdrawn) The restraining device of claim 2, further including:  
coil spring associated with the expandable housing portion which provides column strength to the housing portion and is expandable from the contracted position to the expanded position with the elastic material which forms the housing portion.

15. (Withdrawn) The restraining device of claim 14, wherein:  
the coils of the coil spring extend longitudinally along the length of the expandable housing portion.
16. (Withdrawn) The restraining device of claim 14, wherein:  
the coil spring is made from a material selected from a group including nickel-titanium, spring steel and highly flexible plastic.
17. (Withdrawn) The restraining device of claim 2, further including:  
a ring member disposed near the distal tip of the expandable housing portion.
18. (Withdrawn) The restraining device of claim 17, wherein:  
the ring member has a plurality of undulations and is expandable with the elastic material which forms the housing portion.
19. (Withdrawn) The restraining device of claim 18, wherein:  
the ring member is made from a material selected from a group including nickel-titanium, spring steel and highly flexible plastic.
20. (Previously Presented) The restraining device of claim 3, wherein:  
the expandable housing portion includes a low expansion section with at least one expansion member disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position.
21. (Previously Presented) The restraining device of claim 3, wherein:  
the expandable housing portion includes a plurality of low expansion sections and a plurality of expansion members disposed between low expansion sections.
22. (Original) The restraining device of claim 21, wherein:  
the low expansion sections are made from a material loaded with a material having high radiopacity.

23. (Original) The restraining device of claim 21, wherein:  
the expansion members are made from an elastic material selected from a group which includes polyurethane, silicone, polyisoprene and lower durometer PEBAK.
24. (Original) The restraining device of claim 23, wherein:  
the low expansion sections are made from a material selected from a group including cross-linked HDPE, polyolefin and polyamide.
25. (Original) The restraining device of claim 21, wherein:  
the expansion members extend longitudinally along the length of the expandable housing portion.
26. (Original) The restraining device of claim 25, wherein:  
the expansion members include means for preventing the low expansion sections from tearing as the expandable housing portion expands from the contracted position to the expanded position.
27. (Withdrawn) The restraining device of claim 2, wherein:  
the expandable housing portion includes a distal tip section made from highly elastic material which is expandable and contractible between a contracted position and expanded position.
28. (Withdrawn) The restraining device of claim 27, wherein:  
the distal tip section is made from a more elastic material than the remaining portion of the expandable housing portion.
29. (Withdrawn) The restraining device of claim 28, further including:  
an expandable ring member associated with the distal tip section which is expandable between the contracted position and expanded position and is normally biased to the contracted position.

30. (Withdrawn) The restraining device of claim 29, wherein:  
the ring member is encapsulated within the material forming the distal tip section.

31. (Withdrawn) The restraining device of claim 29, wherein:  
the ring member is attached to the outer surface of the distal tip section.

32. (Withdrawn) The restraining device of claim 29, wherein:  
the ring member is made from materials selected from a group including nickel-titanium, stainless steel and highly elastic plastic.

33-40. (Canceled)

41. (Currently Amended) A restraining device for maintaining a self-expanding medical device on a delivery device, comprising:

a restraining sheath having an expandable housing portion adapted to move between a contracted position and an expanded position and to maintain the self-expanding medical device in a collapsed condition on the delivery device, and a [non-woven] reinforcing member associated with the expandable housing portion to cooperatively provide sufficient strength to the expandable housing portion to maintain the self-expanding medical device in its collapsed condition on its delivery device without the reinforcing member interfering with the ability of the expandable housing portion to move between the contracted and expanded positions.

42. (Currently Amended) The restraining device of claim 41, further including:

a plurality of [non-woven] reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion but which do not interfere with the ability of the expandable housing to move between the contracted and expanded positions.

43. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is embedded in the wall which forms the expandable housing portion.

44. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is an elongated bar-like member made from a material having a stiffness higher than the stiffness of the material used to form the expandable housing portion.
45. (Previously Presented) The restraining device of claim 41, wherein:  
the expandable housing portion is made from an elastic material selected from a group of materials which includes silicone, polyurethane, polyisoprene, and low durometer PEBAK.
46. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is made from a material selected from a group including stainless steel, polymeric material, and nitinol.
47. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is loaded with a material having high radiopacity.
48. (Previously Presented) The restraining device of claim 41, wherein:  
the expandable housing portion is made from a substantially tubular-shaped material which is highly elastic and includes a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion.
49. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is molded within the material used to form the expandable housing portion.
50. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member is attached to the surface of the expandable housing portion.
51. (Previously Presented) The restraining device of claim 41, wherein:  
the reinforcing member helps to bias the expandable housing portion in the contracted position.

REMARKS

This Amendment is in response to the final Office Action dated September 11, 2006.

Claims 3-32 and 41-51 are pending in this application. Claims 14-19 and 27-32 have been withdrawn from consideration in view of an earlier election of species requirement and claims 1, 2 and 33 - 40 were previously canceled without prejudice. By this Amendment, claims 3, 4, 41 and 42 have been amended to delete the term "non-woven" from the claims. These amendments were not made for the purpose of distinguishing the presently claimed invention over the art of record. Favorable reconsideration of all of the pending claims is respectfully requested in view of the remarks below.

The Examiner has rejected claims 3-13, 20-26, 41-51 under 35 U. S. C. 112, first paragraph as failing to comply with the written description requirement. The Examiner believes that the term "non-woven reinforcing member" recited in the present claims constitutes new matter. Applicants note that the Examiner has acknowledged that the specification lists materials for the reinforcing member which are non-woven materials. However, in order to expedite the prosecution of this application, Applicants have amended the claims, without prejudice, to delete the term "non-woven" from the claims. In light of these amendments, Applicants respectfully request the Examiner to withdraw the Section 112, first paragraph rejection of the above-identified claims.

The Examiner has rejected claims 3-13, 20-26 and 41-51 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,544,279 to Hopkins et al. (the "Hopkins patent") in view of U.S. Patent No. 6,123,715 to Amplatz (the "Amplatz patent") and U.S. Patent No. 6,517,765 to Kelley (the "Kelley patent"). Applicants again strongly disagree with the Examiner's position. First, it is noted that the Hopkins patent fails to show an expandable housing portion made primarily from an elastic material, as recited in independent claim 3, or a housing portion movable between an expanded position and a contracted position, as recited in independent claim 41. Rather, the Hopkins patent discloses a housing portion made from a non-elastic material since the distal end of the sheath 584 remains plastically deformed in an expanded position after the expander 590 is moved into the sheath 584. Reference is made to Figure 23B of the Hopkins patent which clearly shows that the distal end of the sheath 584 remains plastically deformed in an expanded position after being stretched by the expander 590.

Applicants note that Figure 23B shows a large gap formed between the wall of the sheath 584 and the filter 480 after the filter is retrieved into the sheath. If the sheath 584 was made from an elastic material, then there would be no gap formed between the sheath wall and filter 580 since the elasticity of the material would bring the distal end of the sheath 584 back into direct contact with the filter 580. Rather, the sheath 584 disclosed in the Hopkins patent is made from a much stiffer material which remains plastically deformed after being stretched. Accordingly, the sheath 584 shown in the Hopkins patent is not made from an elastic material and is not capable of movement between an expanded and contracted position. The sheath 584 of the Hopkins patent is only capable of moving from a contracted position to an expanded position where it remains in an expanded configuration. As is shown in Figure 23B, the sheath 584 does not move back to its contracted position and thus does not move between expanded and contracted positions as recited in claim 41. Accordingly, Applicants submit that for at least these reasons, the Hopkins patent fails to disclose the basic elements recited in the pending claims. The other cited secondary references also fail to disclose the use of an elastic housing portion. Therefore, the combination of references suggested by the Examiner simply fails to achieve the structure recited in the pending claims. In view of these arguments, Applicants respectfully request that the rejections of all of the claims under 35 U.S.C. 103(a) be withdrawn.

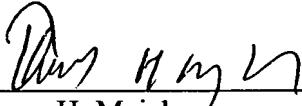
In view of the apparent allowability of generic claims, Applicants respectfully request the Examiner to reconsider claims 14-19 and 27-32 which were previously withdrawn in response to an earlier election of species requirement.

In view of the foregoing, it is respectfully urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above amendments and remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

FULWIDER PATTON LLP

By:   
Thomas H. Majcher  
Registration No. 31,119

THM/lm

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FULWIDER PATTON LLP  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,295	06/29/2001	William J. Boyle	ACS-56001 (26361)	1994
24201	7590	01/04/2007	EXAMINER	
FULWIDER PATTON 6060 CENTER DRIVE 10TH FLOOR LOS ANGELES, CA 90045			MITCHELL, TEENA KAY	
		ART UNIT		PAPER NUMBER
		3771		
		MAIL DATE		DELIVERY MODE
		01/04/2007		PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

FINAL REJECTION

2-MONTH RESPONSE DUE: \_\_\_\_\_

3-MONTH RESPONSE DUE: \_\_\_\_\_

NOTICE OF APPEAL DUE:

(6-MONTH PERIOD ENDS) March 11, 2007

**Advisory Action**  
**Before the Filing of an Appeal Brief**

Application No.

09/897,295

Applicant(s)

BOYLE ET AL.

Examiner

Teena Mitchell

Art Unit

3771

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

THE REPLY FILED 13 November 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1.  The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a)  The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2.  The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3.  The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a)  They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b)  They raise the issue of new matter (see NOTE below);  
 (c)  They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d)  They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4.  The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5.  Applicant's reply has overcome the following rejection(s): 112 first paragraph.

6.  Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7.  For purposes of appeal, the proposed amendment(s): a)  will not be entered, or b)  will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 3-13, 20-26 and 41-51.

Claim(s) withdrawn from consideration: 14-19 and 27-32.

AFFIDAVIT OR OTHER EVIDENCE

8.  The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9.  The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10.  The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11.  The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

12.  Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_

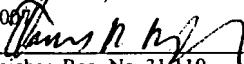
13.  Other: See Continuation Sheet.

  
 Teena Mitchell  
 Primary Examiner  
 Art Unit: 3771

Continuation of 13. Other: Applicant's arguments are not persuasive the examiner maintains the previous rejection, note the Final Rejection at which time the arguments were addressed.

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MAIL STOP APPEAL BRIEF-PATENTS, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on March 2, 2007.

  
Thomas H. Majcher, Reg. No. 31,119

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	: 09/897,295	Confirmation No. 1994
Applicant	: William J. Boyle et al.	
Filed	: June 29, 2001	
Title	: DELIVERY AND RECOVERY SHEATHS FOR MEDICAL DEVICES	
Art Unit	: 3743	
Examiner	: Mitchell, Teena Kay	
Docket No.:	: ACSES 56001 (2636P)	Los Angeles, California
Customer No.	: 24201	March 2, 2007

MAIL STOP APPEAL BRIEF-PATENTS  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

NOTICE OF APPEAL FROM THE EXAMINER  
TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Dear Sir:

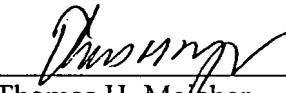
Applicant hereby appeals to the Board of Patent Appeals and Interferences from the decision of the Examiner dated January 4, 2007, rejecting each of pending claims 3-13, 20-26 and 41-51.

A check in the amount of \$500 is enclosed herewith for the fee for this Notice of Appeal. The Commissioner is hereby authorized, however, to charge any additional fees

which may be required, or credit any overpayment, to Deposit Account No. 06-2425. A duplicate copy of this paper has been enclosed.

Respectfully submitted,

FULWIDER PATTON LLP

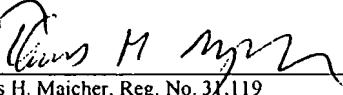
By:   
Thomas H. Malcher  
Registration No. 31,119

Howard Hughes Center  
6060 Center Drive, Tenth Floor  
Los Angeles, CA 90045  
Telephone: (310) 824-5555  
Facsimile: (310) 824-9696  
Customer No. 24201

158190.1

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

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Thomas H. Majcher, Reg. No. 37,119

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	: 09/897,295	Confirmation No. 1994
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Customer No.	: 24201	March 2, 2007

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

REQUEST FOR TWO-MONTH EXTENSION OF TIME

Dear Sir:

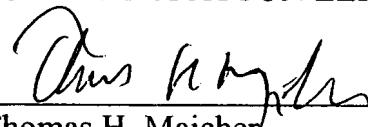
Applicants respectfully request a two-month extension of time to respond to the Final Office Action dated September 11, 2006 and the Advisory Action dated January 4, 2007 in the above-identified application.

The requisite fee of \$450.00 pursuant to 37 C.F.R. §1.136(a) is enclosed herewith.  
Please charge any additional fee or credit any overpayment to our Deposit Account  
No. 06-2425. A duplicate copy of this paper is enclosed.

Respectfully submitted,

FULWIDER PATTON LLP

By:

  
Thomas H. Majcher

Registration No. 31,119

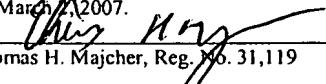
THM:lm

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158199.1

(2)

**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8**

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Thomas H. Majcher, Reg. No. 31,119

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appln. No. : 09/897,295  
Applicant : William J. Boyle et al.  
Filed : June 29, 2001  
Title : DELIVERY AND RECOVERY SHEATHS  
FOR MEDICAL DEVICES  
Art Unit : 3743  
Examiner : Mitchell, Teena Kay

Docket No.: : ACSES 56001 (2636P) Los Angeles, California  
Customer No. : 24201 March 2, 2007

MAIL STOP APPEAL BRIEF-PATENTS  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

**INTRODUCTION**

The present invention is directed to delivery and recovery sheaths for use with medical devices which deliver self-expanding medical devices, such as stents and vascular grafts, for implantation in a patient's vasculature. The present invention can be used with other medical devices, such as an embolic filtering device, which generally includes a self-expanding filter basket disposed on a guide wire. The restraining device of the present invention can be used to deliver the filtering device or stent to the target location in the patient's anatomy and/or to collapse and retrieve the filtering device once the interventional procedure has been completed.

The restraining device includes a restraining sheath having an expandable housing portion adapted to collapse and hold the self-expanding medical device. The expandable housing portion is made from an elastic material to hold the medical device in place and prevent premature deployment. The housing portion of the sheath acts to "encapsulate" the medical device, thus preventing it from being released from the sheath until the physician is ready to do so. When the present invention is utilized as a recovery sheath to recover a filtering device, the housing portion will contract to its smallest diameter as it tracks along the guide wire to reach the embolic filtering basket. As a result, the tip of the sheath should not scrape the walls of the body vessel causing a "snowplow" effect as the sheath is being advanced over the guide wire. Once the filtering basket is retrieved, the elasticity of the housing portion encapsulates the basket to prevent emboli trapped in the basket from "back washing" into the patient's vasculature.

The expandable housing portion includes one or more reinforcing members that provide additional column strength to the housing portion but do not interfere with the radial expansion or contraction of the elastic housing. These reinforcing members provide additional column strength which permits the housing portion to be made from a highly elastic material that would otherwise buckle when subjected to an applied axial force. Various configurations of this reinforcing member are recited in the dependent claims.

#### NOTICE OF APPEAL

A Notice of Appeal from the final Office Action of September 11, 2006 is being filed concurrently herewith along with the appropriate fee.

#### ISSUES ON APPEAL

At issue is whether claims 3-13, 20-26 and 41-51 are unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,544,279 to Hopkins et al. (the "Hopkins patent") in view of U.S. Patent No. 6,123,715 to Amplatz (the "Amplatz patent") and U.S. Patent No. 6,517,765 to Kelley (the "Kelley patent").

The Hopkins patent discloses a retrieval sheath including an expandable housing portion used to retrieve a filter. The Examiner has taken the position that the Hopkins patent discloses a housing portion made primarily from an elastic material which is movable between a contracted position and expanded position, but has admitted that the Hopkins patent fails to disclose a

reinforcing member which provides additional column strength to the housing portion but does not interfere with the expansion or contraction of the housing portion. All of the pending claims include the recitation of a reinforcing member. The Amplatz patent simply discloses a method for forming intravascular devices using a resilient metal fabric. The Examiner relies on a statement appearing in the Amplatz patent that describes the metal fabric used in the Amplatz method as being a tubular braid that has been used in the medical device field to reinforce the walls of guiding catheters (See Column 3, lines 39-48 of the Amplatz patent). The Kelley patent is directed to a method for fabricating flexible and reinforcing tubing and simply teaches that the pitch and/or braid pick counts of the woven fabric and braid can be selected to affect the flexibility of the tubing into which they are formed. The Examiner has taken the position that it would have been obvious to modify the expandable housing portion of the Hopkins device by adding the woven braids disclosed in the Amplatz and Kelley patents. However, Appellant submits that the housing portion disclosed in the Hoskins patent already possesses sufficient column strength and that there would be no need or reason to utilize reinforcing members to increase column strength of the tubing used to form the housing.

A copy of the pending claims is attached hereto as Exhibit A. A copy of the drawings is attached hereto as Exhibit B. A copy of the final Office Action dated September 11, 2006 is attached hereto as Exhibit C. A copy of the Advisory Action dated January 4, 2007 is attached hereto as Exhibit D. A copy of the Hopkins patent is attached as Exhibit E. A copy of the Amplatz patent is attached as Exhibit F. A copy of the Kelley patent is attached as Exhibit G.

### ARGUMENT

Claims 3-13, 20-26 and 41-51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Hopkins patent in view of the Amplatz patent and the Kelley patent. The Examiner relies on the embodiment of Figures 23A and 23B in the Hopkins patent as the primary reference. First, it is noted that the retrieval sheath 592 and expandable end region 594 (the housing portion) of the Hopkins device already possesses sufficient column strength as evidenced when the expander 590 moves into the end region 594 to radially expand it in order to form a larger opening to retrieve the filter 580.

Figures 23A and 23B of the Hopkins patent, relied upon by the Examiner in rejecting the pending claims, are reproduced herein.

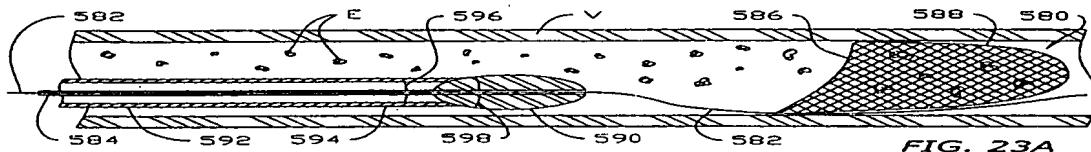


FIG. 23A

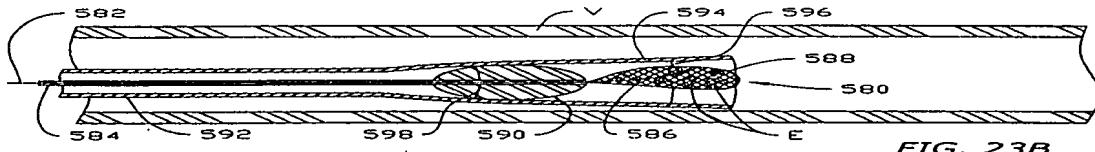


FIG. 23B

Reference is initially made to Figure 23B of the Hopkins patent which clearly shows that the distal end region 594 of the retrieval sheath 592 remains "unbunched" after being radially stretched by the expander 590. The end region 594 of the retrieval sheath 592 must possess sufficient column strength in order to allow the expander 590 to move within the opening to radially expand the tubing. Otherwise, if the end region 594 did not possess enough column strength, then the end region 594 would "bunch" upon itself, much like the bellows of an accordion, when the expander 590 contacts the end region 594 and applies an axial force.

The Hawkins patent thus fails to disclose the use or need for **any** reinforcing member with its housing since the housing already has sufficient column strength to retrieve the filter 580. The sheath 592 already possess sufficient column strength as evidenced by the expander's ability to radially expand the end region 594 without causing bunching. If the end region 594 did not possess sufficient column strength, then the expander 590 would crush the tubing longitudinally as the expander 590 is drawn into the end region 594. Therefore, one skilled in the art would see no need or reason to increase the column strength of the Hopkins retrieval sheath 592 with any type of reinforcing member.

Even assuming *arguendo* that one would still want to increase the column strength of the Hopkins sheath 584, claims 1 and 41 require the reinforcing member to increase the column strength of the housing portion without interfering with the expansion or contraction of the housing. The Amplatz patent simply teaches that woven braids have been used to reinforce the walls of a guiding catheter. Guiding catheters are generally designed to be laterally flexible and will revert to a pre-formed shape to position a catheter in the patient's vasculature. In this regard,

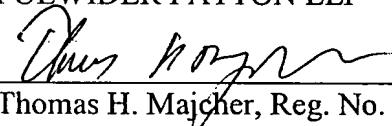
the guiding catheter will be inserted into the patient's vasculature in a relative linear configuration and will revert to its pre-formed shape after reaching its target location. This requires flexibility along the length of the guiding catheter, but not radial expandability, since the tubular structure of the guiding catheter is not designed to expand radially. For this reason, tubular braids have been used to reinforce the wall of the guiding catheter since the intertwining braid geometry is designed to inhibit expansion, but allows lateral or longitudinal flexibility. Simply put, the use of a woven braid with an expandable housing would inhibit radial contraction and expansion of the housing.

The sheath in the Hawkins patent is designed to radially expand as it contacts the expander. However, a woven braid placed on or into an expandable sheath would inhibit the sheath from expanding or contracting radially. The Kelley patent merely teaches that the pitch and/or braid pick counts of the woven braid can be selected to affect the flexibility of the tubing into which they are formed. Therefore, lateral flexibility can be changed. However, woven braids or fabrics generally inhibit expansion or contraction of tubing. Therefore, while one can increase or decrease the lateral flexibility of the tubing by varying the pitch or braid count, the woven braid or fabric still inhibits expansion and contraction of tubing. Therefore, the combination of the Hopkins patent with either the Amplatz or Kelley patent fails to create the structure recited in the pending claims.

In summation, the Hopkins patent fails to disclose the basic elements recited in the pending claims. Moreover, there would be no need or reason to add reinforcing members to the Hopkins sheath. The Amplatz and Kelley patents only disclose structure which would inhibit expansion and contraction of the housing portion.

Respectfully submitted,  
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